IN THE COURT OF COMMON PLEAS OF MONTGOMERY COUNTY, PENNSYLVANIA

INTERNATIONAL UNION OF OPERATING ENGINEERS
LOCAL 542

vs.

MALLINCKRODT ARD INC FKA QUESTCOR
PHARMACEUTICALS INC

NO. 2018-14059

NOTICE TO DEFEND - CIVIL

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you. You are warned that if you fail to do so the case may proceed without you and a judgment may be entered against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

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CIVIL COVER SHEET

State Rule 205.5 requires this form be attached to any document commencing an action in the Montgomery County Court of Common Pleas. The information provided herein is used solely as an aid in tracking cases in the court system. This form does not supplement or replace the filing and service of pleadings or other papers as required by law or rules of court.

Name of Plaintiff/Appellant's Attorney: DONALD E HAVILAND JR, Esq., ID: 66615

Self-Represented (Pro Se) Litigant [ ]

Class Action Suit [ ] Yes [X] No

MDJ Appeal [ ] Yes [X] No

Money Damages Requested [X]

Commencement of Action:

Complaint

Amount in Controversy:

More than $50,000

Case Type and Code

Contract:

Other

Other: BREACH OF CONTRACT

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International Union of Operating Engineers Local 542

IN THE COURT OF COMMON PLEAS
FOR MONTGOMERY COUNTY, PENNSYLVANIA

INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
1375 Virginia Drive, Suite 102
Fort Washington, PA 19034
Plaintiff

v.

MALLINCKRODT ARD, INC.
formally known as
QUESTCOR PHARMACEUTICALS, INC.
675 McDonnell Blvd.
Hazelwood, MO 63042

MALLINCKRODT PLC
3 Lotus Park, the Causeway
Staines-upon-Thames,
Surrey, TW18 3 AG

EXPRESS SCRIPTS HOLDING COMPANY
1 Express Way
St. Louis, MO 63121

EXPRESS SCRIPTS, INC.
1 Express Way
St. Louis, MO 63121

Civil Action No.:

JURY TRIAL DEMANDED

CURASCRIPT, INC.
6272 Lee Vista Boulevard
Orlando, FL 32822

CURASCRIPT SD
255 Technology Park
Lake Mary, FL 32746

ACCREDO HEALTH GROUP, INC.
1640 Century Center Parkway
Memphis, TN 38134

and

UNITED BIOSOURCE CORPORATION,
***now known as* UNITED BIOSOURCE LLC,**
***a wholly owned subsidiary of* UNITED BIOSOURCE HOLDINGS, INC.**
920 Harvest Drive
Blue Bell, PA 19422

Defendants.

NOTICE TO DEFEND

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TABLE OF CONTENTS

Page

CIVIL ACTION COMPLAINT

Plaintiff, International Union of Operating Engineers Local 542 ("IUOE Local 542", or "Plaintiff"), by and through its undersigned counsel, alleges as follows:

1. IUOE Local 542 brings this action to challenge an unjust, unfair, deceptive, and anti-competitive scheme by Defendants Mallinckrodt ARD Inc., formally known as Questcor Pharmaceuticals, Inc. ("Questcor") and its parent company, Mallinckrodt plc (collectively "Mallinckrodt"), along with Mallinckrodt's exclusive agent for the delivery of its products Express Scripts Holding Company and Express Scripts, Inc. (together referred to as "ESI"), including their three (3) wholly-owned subsidiaries: CuraScript, Inc. and CuraScript, SD. ("CuraScript"), Accredo Health Group, Inc. ("Accredo") and United BioSource Corporation, now known as United BioSource LLC, a wholly owned subsidiary of United BioSource Holdings, Inc. ("UBC")(collectively referred to as "Express Scripts").

2. Mallinckrodt manufactures, markets, distributes and sells H.P. Acthar, NDC Nos. 63004-8710-01 and 63004-7731-01 ("Acthar"). Acthar is the only therapeutic adrenocorticotropic hormone ("ACTH") product sold in the United States. Mallinckrodt is the sole provider in the United States of approved ACTH drugs. Thus, Mallinckrodt is a monopolist.

3. Mallinckrodt acquired its Acthar monopoly in 2001 when Questcor purchased Acthar from Aventis for $100,000. By 2014, when Mallinckrodt purchased Questcor, the value of that Acthar monopoly was $5.9 billion—the price paid for the single-product company. This stark increase in value was not due to any change in the Acthar being sold. The formulation of the drug has never changed. The only change between 2001 and 2014 was the price.

4. This case does not seek to challenge the lawfulness of Mallinckrodt's monopoly. It seeks to challenge the lawfulness of Mallinckrodt's exercise of its monopoly power by taking

actions to maintain and enhance that monopoly power in violation of Pennsylvania law.

5. The issue is also not whether Mallinckrodt possessed monopoly power for Acthar. It is also whether Mallinckrodt's actions in contracting with the largest agent of its leading customers, Express Scripts, and in acquiring the only competitive product in the marketplace, Synacthen, constitute unlawful efforts to retain, maintain and enhance Mallinckrodt's monopoly power over Acthar in the ACTH market. As described below, the Federal Trade Commission and a competitor of Mallinckrodt both charged the company with antitrust, which charges Mallinckrodt chose to settle rather than fight. The actions and omissions underlying these charges of antitrust form the bases of the unlawful conduct charged in this Complaint under Pennsylvania law.

6. Acthar is a "specialty pharmaceutical". Unlike most prescription drugs, it is not sold in retail pharmacies, nor is it distributed through wholesalers to retail pharmacies. Instead, it is distributed only through "specialty pharmacy distributors" ("SPDs") and "specialty pharmacy providers" ("SPPs").

7. One of the largest SPDs in America is ESI's CuraScript, which ESI has owned since 2004.

8. In 2007, Mallinckrodt decided to embark on a "new strategy" and it changed its distribution of Acthar. Rather than continue to distribute Acthar to the existing distribution network available for specialty drugs, Mallinckrodt decided to limit Acthar distribution exclusively through ESI's CuraScript. In effect, Mallinckrodt contracted with the agent of its leading customers, and the largest SPD at the time, in order to create an exclusive arrangement whereby both companies would share the financial rewards of the Acthar monopoly through exorbitantly higher prices.

9. Immediately after agreeing to the exclusive arrangement, Mallinckrodt and Express Scripts agreed to raise the price of Acthar from about $2,062.79 per vial of 80 units/ml, 5ml before August 2007 to about $29,086.25 per vial thereafter. As a result, Mallinckrodt was able to charge inflated prices for Acthar to Express Scripts' clients, including IUOE Local 542.

10. IUOE Local 542 has spent approximately $153,775.95 for just 5 administrations of Acthar given to 3 separate adult patients. The new prices of these administrations as paid for by IUOE Local 542 were as follows: $26,095.28 on July 5, 2011 for 1 patient, $60,846.04 on March 13, 2013 for 2 administrations to a second patient, and $32,180.68 on July 29, 2014 and $34,653.95 on July 9, 2015 for separate administrations to a third patient. When Mallinckrodt acquired the Acthar monopoly from Aventis, the cost of an individual vial was just $40.00. Just prior to Mallinckrodt's exclusive agreement with Express Scripts and CuraScript, the cost of an individual Acthar vial was around $2,000. IOUE Local 542 thus paid more for Acthar than it otherwise would have paid in the absence of Mallinckrodt's unlawful actions with Express Scripts to maintain and enhance its monopoly power, and to conspire and agree with Express Scripts to defraud IUOE Local 542. The precise amount of IUOE Local 542's damages will be determined after discovery.

11. For this reason, IUOE Local 542 brings this case to obtain declaratory and injunctive relief and to recover monetary damages. IUOE Local 542 sues all Defendants for violations of Pennsylvania's consumer fraud laws, and common law fraud, unjust enrichment and aiding and abetting. IUOE Local 542 also sues Express Scripts for breach of contract, promissory estoppel and breach of the duty of good faith and fair dealing.

JURISDICTION AND VENUE

12. IUOE Local 542 brings this action pursuant to the consumer protection laws of Pennsylvania, as well as the common law of Pennsylvania. No aspect of the claims asserted in this Complaint is brought pursuant to any federal law, including, but not limited to, RICO, the Sherman Act, or the Clayton Act, and thus no federal question is raised by any of Plaintiff's claims asserted. The mention of Mallinckrodt's violations of antitrust laws is only intended to describe the fact the company has been sued by both the FTC and Retrophin in related lawsuits for the same conduct, which lawsuits the company settled, and to distinguish the claims asserted in this state case from those asserted by other plaintiffs in federal court. To the extent any of Plaintiff's claims or factual allegations herein may be construed to have stated any claim under federal law, such claim is expressly and undeniably disavowed and disclaimed by Plaintiff. Moreover, to the extent any of Plaintiff's claims or factual allegations herein are urged by any of the Defendants to have stated any claim under federal law, Plaintiff expressly disavows such claims or allegations and reserves the right to modify this Complaint to conform its claims.

13. This Court has personal jurisdiction over Plaintiff and its members and beneficiaries because they reside in Pennsylvania and have purchased and reimbursed for Acthar and other drugs within the Commonwealth of Pennsylvania.

14. This Court has jurisdiction over the Defendants because they are present and/or conduct substantial business in this Commonwealth, have registered to conduct business here, have had systematic and continuous contacts with this Commonwealth, and/or have agents and representatives that can be found in this Commonwealth.

15. The Court has jurisdiction over the Defendants because they have had sufficient minimum contacts with and/or have purposefully availed themselves of the laws and markets of

the Commonwealth of Pennsylvania through, among other things, their distribution, marketing and sales of Acthar to IUOE Local 542 and other residents of Pennsylvania.

16. Furthermore, by the Express Scripts, Inc. Pharmacy Benefit Management Agreement (hereinafter the "ESI PBM Agreement") at issue here, Express Scripts and IUOE Local 542 agreed that the ESI PBM Agreement "will be construed and governed in all respects according to the laws in the Commonwealth of Pennsylvania, without regard to the rules of conflict of laws thereof".

17. Venue is proper in this County because Plaintiff and Defendant UBC are situated in this County, and the other Defendants transact business in this County. Venue is also proper because a substantial part of the events giving rise to the Plaintiff's claims occurred in this County. Defendants engaged in substantial conduct relevant to the Plaintiff's claims and caused harm to Plaintiff in Montgomery County, Pennsylvania.

THE PARTIES

PLAINTIFF

18. IUOE Local 542 is a Taft-Hartley union fund providing health and welfare benefits to its members and their families. IUOE Local 542 resides at 1375 Virginia Drive, Suite 100, Fort Washington, PA 19034, which is situated in Montgomery County, Pennsylvania.

19. IUOE Local 542 has represented the interests of working men and women in Eastern Pennsylvania since 1935, including heavy equipment operators in the building and construction industry, along with C & D-Branch Division members who are employed at quarries, landfills, equipment dealers, shipyards, breweries, manufacturing plants, airports, bridges, and public works.

20. Three such members of IUOE Local 542 had serious medical conditions, for which Acthar was indicated as a treatment option. These members of IUOE Local 542 received Acthar directly from Mallinckrodt's authorized agent, Express Scripts. IUOE Local 542, which pays the health care benefits of its members, including specialty pharmacy drugs, then paid for these administrations of Acthar.

21. The sum total of the 4 prescriptions (5 administrations) paid for by IUOE Local 542 was $153,775.95. The administrations were given to the below 3 adult patients on the listed dates, for which IUOE paid the listed amounts based on the Average Wholesale Price ("AWP") as established by Defendants:

Patient	NDC	Date Filled	AWP	Billed Amount	Co-Pay
Patient 1	63004-7731-01	2011/07/01	$30,783.60	$26,095.28	$40.00
Patient 2	63004-8710-01	2013/03/13	$71,715.00	$60,846.04	$40.00
Patient 3	63004-8710-01	2014/07/29	$37,951.20	$32,180.68	$40.00
Patient 3	63004-8710-01	2015/07/09	$40,840.80	$34,653.95	$20.00

22. IUOE Local 542 paid $153,775.95 directly to Express Scripts, as agent for Mallinckrodt. These monies were then transferred by Express Scripts to Mallinckrodt, after Express Scripts deducted its undisclosed (to Plaintiff), but agreed-upon (with Mallinckrodt), share of the revenues.

DEFENDANTS

23. Questcor Pharmaceuticals, Inc. ("Questcor") was acquired by Mallinckrodt on August 14, 2014 for $5.9 billion, after paying only $100,000 for Questcor's lone product 13 years earlier. Following the acquisition, Questcor became a wholly-owned subsidiary of

Mallinckrodt and its name was changed to Mallinckrodt ARD Inc. Mallinckrodt ARD is a biopharmaceutical company incorporated in California, with offices located at 675 McDonnell Boulevard, Hazelwood, Missouri 63042. Mallinckrodt ARD now has locations in Hampton, New Jersey and Bedminster, New Jersey. For clarity, where necessary, the entity that existed prior to the Mallinckrodt acquisition is herein referred to as "Questcor".

24. At the time of the Mallinckrodt acquisition, Questcor's only product sold in the United States was Acthar. As of the date of this Complaint, Mallinckrodt continues to manufacture, distribute and sell Acthar directly to patients, exclusively through Express Scripts, by a program known as the "Acthar Support and Access Program" ("ASAP") described below.

25. Defendant, Mallinckrodt plc ("Mallinckrodt plc"), is an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, the Causeway, Staines-upon-Thames, Surrey, TW18 3 AG.

26. Mallinckrodt plc, Mallinckrodt ARD and Questcor are collectively referred to as "Mallinckrodt".

27. Defendants Express Scripts, Inc. and Express Scripts Holding Company are Delaware Corporations with their principle executive offices located at 1 Express Way, Saint Louis, Missouri 63121. Together, Express Scripts, Inc. and Express Scripts Holding Company are referred to as "ESI".

28. Defendant CuraScript, Inc. is a Delaware corporation with its principal place of business at 6276 Lee Vista Blvd., Orlando, FL 32822, and is a wholly-owned subsidiary of ESI. CuraScript, Inc. was acquired by ESI in January 2004. CuraScript, Inc. operates as an SPP.

29. In October 2005, Express Scripts acquired the capital stock of Priority Healthcare Corporation ("Priority") for $1.3 billion. The acquisition was accomplished through the merger of wholly-owned CuraScript, Inc. with and into Priority. Priority is headquartered at 255 Technology Park, Lake Mary, Florida. Since the acquisition, Priority has done business as Priority Healthcare Distribution, Inc. d/b/a CuraScript SD Specialty Distribution ("CuraScript SD"). (CuraScript, Inc. and CuraScript SD are collectively referred to as "CuraScript".) The combined Priority and CuraScript became one of the nation's largest specialty pharmacy and distribution companies with more than $3 billion in annual revenue.

30. CuraScript SD's corporate headquarters are now located at 255 Technology Park, Lake Mary, Florida 32746, the address of Priority. This is the same address patients are required to mail any revocation of the broad authorization granted by patients to Mallinckrodt and UBC via the Acthar Start Form (*see,* Exhibit "A" hereto). CuraScript is Mallinckrodt's exclusive SPD for Acthar.

31. Defendant Accredo Health Group, Inc. ("Accredo") is a wholly-owned subsidiary of ESI. Accredo became a wholly-owned subsidiary of Medco Health Solutions, Inc. ("Medco") on August 18, 2005, months before ESI acquired Priority, and then became part of ESI when ESI acquired Medco in April 2012.

32. Accredo is a Delaware corporation with its corporate headquarters at 1640 Century Center Parkway, Memphis, Tennessee 38134. Accredo also has operations in Warrendale, Pennsylvania, Corona, California, Greensboro, North Carolina, Orlando, Florida, Indianapolis, Indiana, and Nashville, Tennessee.

33. Defendant United BioSource Corporation ("UBC") is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422. UBC was

a wholly-owned subsidiary of ESI. UBC was acquired by ESI in 2012 as part of the Medco merger.

34. On November 27, 2017, ESI announced that it sold UBC to Avista Capital Partners, a private equity firm. UBC is now known as United BioSource LLC, a wholly-owned subsidiary of United BioSource Holdings, Inc.

35. UBC is described as Mallinckrodt's "agent" on the Acthar Start Form (Exhibit "A" hereto) which Mallinckrodt employs exclusively to operate the ASAP program and to manage ESI's exclusive distribution, sales and reimbursement of Acthar by its 3 operating arms, CuraScript, Accredo and ESI.

36. As stated in Paragraph 1, ESI, CuraScript, Accredo and UBC are collectively referred to herein as "Express Scripts".

37. Mallinckrodt and Express Scripts are collectively referred to herein as "Defendants", as appropriate.

38. The Defendants' acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

FACTUAL BACKGROUND

39. "I have a Cadillac in my refrigerator." That is how one Acthar patient named Sharon Keller described an unused 5-ml vial of the medication sitting in her kitchen refrigerator.

40. The tale of how a 65-year-old brand medication could rise in price from $40 per vial in 2001 to $40,840.80 per vial by 2015, raising that value of the brand from $100,000 to $5.9 billion, is a story of perhaps the most egregious fraud and monopolistic conduct by a

prescription drug company in United States history.

History of Acthar Development, Distribution and Pricing

41. Acthar was approved by the Food and Drug Administration ("FDA") in 1952 for over fifty conditions, ranging from alcoholism, poison ivy, and radiation sickness to nephrotic syndrome. Over time, with additional evidence-based requirements for prescription drugs, the list was reduced to the present-day nineteen indications.

42. Acthar is adrenocorticotropic hormone ("ACTH"), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed. Acthar was developed by Armour Pharmaceutical Company. As described by the Seventh Circuit in *Armour & Co. v. Wilson & Co.*, 274 F.2d 143, 145-46 (7th Cir. 1960):

> In a human being, . . . (ACTH) appears in the anterior lobe of the pituitary gland located at the base of the brain. When the human body is under stress or attacked by certain diseases, control centers in the brain excite the pituitary, and the pituitary secretes ACTH. In the blood stream the ACTH thus secreted is carried to the adrenal glands situated in the human body above the kidneys. As the ACTH hits the outer wall of the adrenal glands, it stimulates the adrenals to produce a set of chemical substances such as steroids, including the hormones, cortisone and hydrocortisone.
>
> The cortisone hormones then act in the tissues of the body to suppress inflammations and allergic reactions. ACTH thus is used to relieve such conditions as rheumatoid arthritis and allergies. ACTH does not, itself, directly attack disease. However, it stimulates the adrenals which produce more than twenty-eight steroids, and these hormones attack the diseased tissues. When the human body itself does not supply sufficient ACTH, pharmaceutical ACTH can fill the gap.

43. By the 1960s, injectable ACTH medications faced a variety of competing products. *See id.* at 145 ("Both Armour and Wilson manufacture and sell gelatin-ACTH

preparations ... Gelatin-ACTH now constitutes more than 80% [o]f all forms of ACTH products sold by Armour and Wilson. Other companies ... produce similar products").

44. For the majority of the drug's lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved. That factor tended to limit the market for Acthar to treating infantile spasms ("IS") which was originally an "off-label" indication. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at $40 per vial and accounted for less than a million dollars of revenue for Aventis Pharmaceuticals, Inc. ("Aventis"), the then-owner.

45. In 2001, Questcor acquired Acthar from Aventis for only $100,000, but in 2014 Mallinckrodt acquired Questcor for $5.9 billion.

46. Acthar's value was limited because it was the "gold standard" for treating only one condition, infantile spasms ("IS"). IS is a serious condition in infants, but one with an annual patient population of less than 2,000 children per year. However, Acthar was not originally approved by the FDA to treat IS, further limiting its value. A few years later, the IS indication was approved by the FDA.

Mallinckrodt Adopts a "New Strategy" to Restrict
Acthar Distribution to Maintain and Enhance its Monopoly Power over Acthar

47. Acthar is a specialty pharmaceutical distributed directly to patients, like the IUOE Local 542 beneficiaries in this case.

48. For decades, Acthar was distributed to any doctor, hospital, wholesaler or specialty pharmacy who requested the drug to treat seriously ill patients. After Questcor acquired the rights to Acthar, it maintained that broad distribution network.

49. However, on July 2, 2007, Mallinckrodt restricted its distribution from three wholesalers, termed Wholesalers "A", "B", and "C" in its 2007 10-K, to just Express Scripts, the

agent of its largest customers. Mallinckrodt's announcement stated, **"[e]ffective August 1, 2001, Acthar…will be available exclusively through Specialty Pharmacy Distribution**. Acthar Gel will no longer be available from traditional pharmaceutical wholesalers or retail pharmacies." *See* July 2, 2017, "Urgent Product Alert H.P. Acthar Gel" at Exhibit "B" hereto. All distribution would now be done exclusively through CuraScript via the Acthar Support & Access Program ("ASAP"). "[A]ll new Acthar Gel prescriptions should be submitted to the Acthar Support & Access Program." *Id.* All aspects of Acthar distribution were handled by Express Scripts.

50. The goal of this "new strategy" was to lock patients into receiving Acthar through one distribution channel controlled by Mallinckrodt and Express Scripts, and to ensure prescription distribution and payment through one source, Express Scripts. Mallinckrodt has maintained this exclusive arrangement with Express Scripts since 2007. Title, dominion and risk for Acthar remained with Mallinckrodt throughout this time.

51. Mallinckrodt manages its exclusive arrangement with Express Scripts through the ASAP program. ASAP is structured so that Mallinckrodt ships Acthar directly to patients and receives payment directly from the associated third-party payors.

52. Once the patient (or their physician) contacts Mallinckrodt for a prescription of Acthar, they are directed to UBC. Otherwise, patients and/or their providers contact UBC directly, as directed by the Acthar Start Form which is attached as Exhibit "A". UBC then serves as the self-described "hub" for Mallinckrodt and Express Scripts' exclusive arrangement. It confirms the patient's insurance coverage or other source of payment, and then arranges for Acthar to be delivered directly to the patient by CuraScript.

53. The process, which is laid out in Mallinckrodt's Acthar Start Form, requires patient, physician and payor authorization before Mallinckrodt agrees to ship Acthar to patients via ESI/CuraScript. *See* Exhibit "A" hereto. Thus, Express Scripts is not at risk. The Acthar Start Form consists of 3 sections: (1) a section requiring signature by the "HCP" (or health care professional); (2) a patient authorization requiring signature by the "patient or legal representative"; and (3) an information form concerning Acthar indications and usage. The required signature of the patient authorizes "Mallinckrodt and its agents" to do a number of things in relation to the prescription and distribution of Acthar. It further authorizes Mallinckrodt and its agents, "including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, 'Designated Parties')" to provide Acthar and receive payment, among other things.

54. Specifically, the patient authorizes Mallinckrodt, UBC, "or any other operator" of ASAP on behalf of Mallinckrodt, "collectively ('Designated Parties'), to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injecting training." In other words, the patient directly authorizes Mallinckrodt and its agents to ship Acthar to them directly via CuraScript, and authorizes payment by both the patient and any third party payor prior to obtaining the medication. The patient therefore authorizes Express Scripts to bill the payor, such as IUOE Local 542, for Acthar. Ex. "A".

55. Similarly, the physician must "authorize[ ] United BioSource Corporation (UBC), the current operator of the Acthar Support and Access Program (Program), and other designated operators of the program, to perform a preliminary assessment of benefit verification for this

patient…". The physician also "agree(s) that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy." Exhibit "A" hereto.

56. The interaction of all 4 elements of Express Scripts' functions on behalf of Mallinckrodt is described below.

57. Express Scripts is the largest buyers' agent for pharmaceuticals in the United States. Express Scripts has substantial buying power as a result of its representation of the largest number of buyers in the pharmaceutical marketplace.

58. Express Scripts styles itself as a "pharmacy benefit manager" or "PBM", but it does more than simply process claims for prescriptions filled at retail pharmacies. In addition to "retail pharmacy claims processing, formulary management, utilization management and home delivery pharmacy services", Express Scripts offers "specialty services that deliver ... high-cost injectable, infused, oral or inhaled drugs," and "compliance programs, ... drug therapy management programs, [] data analysis, and [] distribution services."[1] Acting "either directly or through its subsidiaries", Express Scripts acts as a direct pipeline from a pharmaceutical manufacturer to the patient, facilitating the direct distribution of prescription drugs from the factory to the patient's home.

59. Express Scripts acts as a manufacturer's direct distributor of specialty drugs to patients because it provides what it calls "integrated specialty services." (emphasis in original).[2] As one Express Scripts executive put it, "we're family." These integrated services include the

[1] Express Scripts Holding Company Annual Report on Form 10-K for the Fiscal Year Ending December 31, 2012.

[2] https://curascriptsd.com/corporate-overview

PBM (ESI), the SPD (CuraScript) and the SPP (Accredo).

60. Express Scripts coordinates all of these functions through its so-called pharmaceutical support services unit, UBC. UBC acts as a " 'hub,' that serves as a centralized point of contact for [] patients [] and prescribers"[3] by "[w]orking hand-in-hand with Express Scripts' specialty pharmacy and specialty distribution organizations, Accredo and CuraScript [],"[4] to coordinate delivery of and reimbursement for specialty pharmaceuticals.

61. In total, UBC operates "an integrated service model that involves UBC . . . manag[ing] multiple system applications that support one product. [UBC's] services include the UBC coordinating center, nurse coordination . . . product fulfillment through Accredo and wholesale fulfillment through CuraScript[]. When a patient is prescribed [a specialty] medication, the doctor sends a referral to the Reimbursement Hub. [UBC's] team serves as the liaison among doctors, patients and insurance companies as [UBC]…navigates[s] the coverage process. [UBC]…ensure[s] a smooth transition from enrollment through shipment of the medication."

62. Part of the reimbursement hub process is coordination with Express Scripts' CuraScript, which acts as an "integrated delivery network" connecting patients to manufacturers through "end-to-end distribution services."[5] Simply put, CuraScript is similar to a FedEx, DHL, or UPS for specialty prescription drugs. CuraScript advertises that it is "recognized by the manufacturing community as [] a reliable partner in the management of brands" through CuraScript's "integrated specialty services," which deliver medications to patients "alongside

[3] http://www.ubc.com/services/loyalty/reimbursement-patient-assistance

[4] http://www.ubc.com/services/loyalty/reimbursement-patient-assistance

[5] https://curascriptsd.com/Rare-Disease-Specialty-Distribution-Program

sister organizations Accredo and UBC."[6]

63. To facilitate these end-to-end distribution services, UBC coordinates CuraScript's activities with Accredo, which provides so-called specialty pharmacy services. By acting as the hub, UBC ensures that a patient whose pharmacy benefits are managed by ESI can get a specialty medication delivered to him or her by coordinating shipment through CuraScript and Accredo and payment through ESI. "As one UBC executive has explained "if UBC is the Hub and Accredo is the [specialty pharmacy] . . . we can send the patient's prescription over to Accredo, and they will not have to duplicate any of our efforts, which another pharmacy would be compelled to do because of risk. Accredo trusts us."

64. Accredo provides specialty pharmacy and related services for patients with certain complex and chronic health conditions. Accredo's staff is comprised of a team of specialty-trained pharmacists, nurses, patient care advocates, social workers and insurance coordinators whom, among other things, "handle everything about" a patients' medications and/or specialty therapy.

65. Along with UBC, Accredo provides: (a) support to orphan and ultra orphan patient populations; (b) HUB employees to navigate insurance requirements, like prior authorizations, for patients and prescribers; (c) clinicians who are available 24/7 to address patient concerns and provide guidance on mitigating adverse events; (d) reimbursement HUB specialists to steer patients to funding solutions, and (e) an integrated solution allowing patients to start therapy twice as fast.

66. Accredo publicly represents that by using Accredo's specialty pharmacy services, plan sponsors like IUOE Local 542 can save money by managing their specialty spend through

[6] https://curascriptsd.com/supplier-relations

Accredo. Accredo further promises patients the most effective and affordable medications while ensuring appropriate utilization, managing unit costs, driving out waste, and reducing related medical expenses. In reality, however, the use of Accredo only insured that IUOE Local 542 would pay the inflated prices for Acthar that Express Scripts agreed with Mallinckrodt to charge.

67. In simple terms, through UBC's coordination with Accredo, CuraScript, and ESI, Express Scripts delivers a prescription drug directly from the manufacturer to the patient, bypassing all impediments to delivery and payment, whether medical, logistical or financial. The most important impediment is the leverage of Express Scripts, as agent for IUOE Local 542 in negotiating with prescription drug companies, like Mallinckrodt, for lower prices.

68. With respect to Acthar, Mallinckrodt has a contract with UBC to coordinate the delivery of Acthar through the ASAP Program. Beginning with its July 2, 2007 announcement, Mallinckrodt directed physicians to prescribe Acthar through the ASAP program. *See* Exhibit "B". In this announcement, Mallinckrodt directed physicians that "all new Acthar [] prescriptions should be submitted to the [ASAP program]." Prescriptions are submitted to the ASAP program through the "Acthar Start Form." *See* Exhibit "A". This form authorizes UBC to coordinate reimbursement with ESI and direct the prescription to a "designated specialty pharmacy." This designated specialty pharmacy is Accredo. Accredo dealt with Local 542's patient members. Part of UBC's activities involve coordinating the shipment of Acthar from CuraScript through Accredo to the patient. Indeed, in order to revoke UBC's authorization to perform these services, the patient must mail a letter to CuraScript's address in Florida.

69. The Acthar distribution arrangement between Express Scripts and Mallinckrodt is illustrated in the following two figures. In Figure 1, the distribution arrangement is described in aggregate.

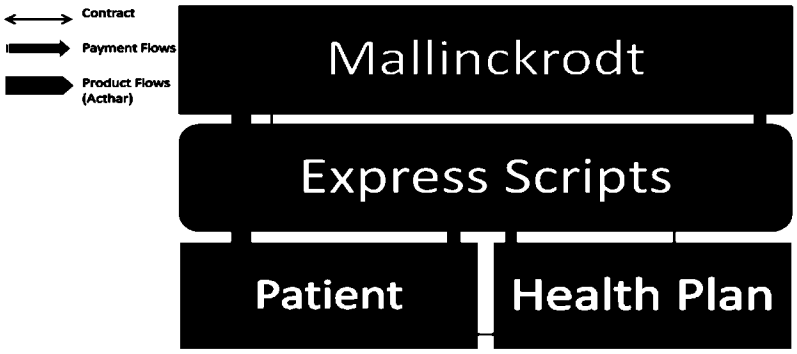

Figure 1

70. Figure 2, below, illustrates how Acthar is prescribed, authorized, distributed and paid for through Express Scripts. Payment flows are represented by green arrows traveling from payor and patient to Mallinckrodt, while product flows are represented by black chevrons flowing from Mallinckrodt to the patient. Although these pass through Express Scripts, payment flows and product flows are ultimately aligned between Mallinckrodt and UBC, Express Scripts' reimbursement hub, through a contract with Mallinckrodt to operate the ASAP program, which ostensibly operates to confirm the medical necessity of the prescription (by Accredo), to arrange payment (to ESI) for shipment (from CuraScript) of Acthar to patients. Through these contractual arrangements, Acthar travels from Mallinckrodt directly to the patient.

71. The patient, on the other hand, has prescription insurance coverage through his or her health plan, such as that provided by IUOE Local 542 to its patient members. In this case, IUOE Local 542 administered the health plan that covered its 3 adult patient members. The health plan has a contract with ESI, which requires ESI to collect payments for the price of Acthar as a "specialty drug".

72. By these arrangements, the Acthar product flows directly from Mallinckrodt through Express Scripts to the patient, while the money flows directly from the patient and payor

through Express Scripts back to Mallinckrodt.

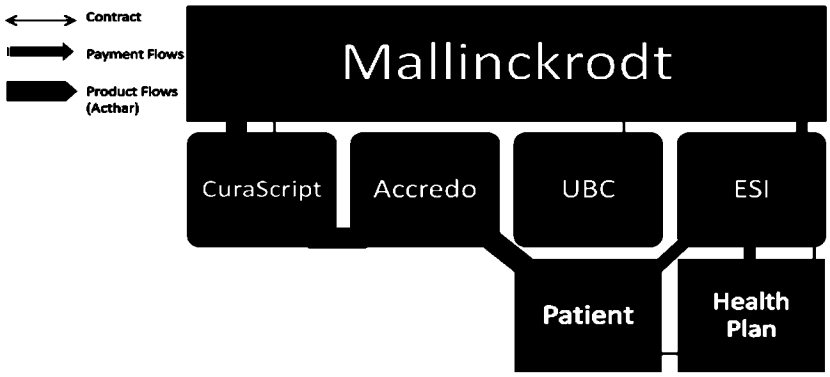

Figure 2

73. Wielding both the largest collection of patients in the United States and a direct shipment channel for specialty drugs, Express Scripts is in a unique position to negotiate the most competitive, discount prices for specialty drugs in the United States. This bargaining power has allowed Express Scripts to push back against attempts by pharmaceutical drug manufacturers to charge inflated prices for drugs above the actual market value of the drugs.

74. However, in this case, Mallinckrodt leveraged and enhanced its monopoly power by limiting the distribution of its sole specialty drug to just one specialty pharmacy distributor, CuraScript, and employing as its agents ESI's Accredo and UBC, along with CuraScript, to coordinate all aspects of the distribution and sales of Acthar: from prescription by the physician, to direct home delivery to the patient, to direct reimbursement by the payor. This allowed Mallinckrodt to raise its prices tenfold initially, and nearly double in the ensuing years, without any pushback from Express Scripts.

75. Mallinckrodt Executive Vice-President Steve Cartt admitted, "'[w]e did some market research,' . . . [t]alking to physicians and others about pricing 'gave us some comfort that the [new] strategy would work, and physicians would continue to use the drug, and payers would

pay' . . . 'The reality was better than we expected.' " *See,* Milt Freudenheim, *Benefit Managers Profit by Specialty Drug Rights*, New York Times, C1, April 19, 2008 (titled, "The Middleman's Markup" in New York Print Ed.)(hereinafter, "Freudenheim").

IUOE Local 542's PBM Contract with Express Scripts

76. IUOE Local 542 contracted with Express Scripts to provide pharmacy benefit services, among other things. During the relevant time period, IUOE Local 542 has been a member of the Delaware Valley Healthcare Coalition ("DVHCC"), which has entered into various "Umbrella Agreements" with ESI for the provision of prescription drug benefit management services. IUOE Local 542 has entered into the "Pharmacy Benefit Management Agreement" with Express Scripts ("ESI PBM Agreement").

77. The term of the ESI PBM Agreement was for three years from the commencement date. Accordingly, on February 1, 2012, DVHCC entered into an Umbrella Agreement with ESI, which included an ESI PBM Agreement, which IUOE Local 542 agreed to. ESI and IUOE Local 542 then entered into an ESI PBM Agreement dated June 1, 2015. This agreement was then updated and amended in May 2015, and then again in February 2017.

78. Under the ESI PBM agreement, ESI agreed to provide IUOE Local 542 with pharmacy benefit management services. Principal among those services has been the containment of the costs of prescription drugs, especially brand name and specialty drugs, required by the members of IUOE Local 542 for the treatment of their medical conditions, and paid for by IUOE Local 542.

79. ESI bargained with IUOE Local 542 to serve as its exclusive specialty pharmacy provider and distributor, in order to contain and reduce IUOE Local 542's prescription drug costs.

80. One of the specialty medications that IUOE Local 542 contracted with ESI to supply exclusively was Mallinckrodt's Acthar Gel injection. For all years during the relevant time period, Acthar has been listed as a "specialty drug" in the ESI PBM Agreement and was identified for use to treat. Express Scripts alone determines what makes a particular drug "special" for inclusion in its "specialty product list". ESI maintains the list of specialty products and their reimbursement rates. Such rates have been determined by ESI to be based on the AWP for the drugs. "ESI updates the list of Specialty Drugs and assigns a default AWP to each drug by therapeutic category as new drugs are brought to market."

81. The ESI PBM Agreement purports to provide IUOE Local 542 members with the opportunity to obtain Acthar "at a Participating Pharmacy", and not through CuraScript. In actuality, and for all years since 2007, Acthar has only been available through CuraScript, but ESI never disclosed such fact to IUOE Local 542. ESI also never disclosed the fact of its exclusive arrangement with Mallinckrodt beginning in 2007 and continuing through the present, and in fact misrepresented this fact in its contract with IUOE Local 542. This exclusive arrangement has caused the AWP-based prices of Acthar to increase each year, including at the exorbitant amounts described herein. In fact, ESI's "list of specialty products" attached to the ESI PBM Agreement specifically, and deceptively, lists Acthar as available at participating pharmacies for a reimbursement rate of AWP minus 12%, as opposed to through CuraScript exclusively, at a rate of AWP minus 15%. Acthar is not listed as a "limited distribution" drug, which it clearly has been since 2007.

82. IUOE Local 542 agreed to pay ESI certain reimbursement rates for specialty pharmacy drugs as established by ESI for each such drug. The reimbursement rates for each drug varied from a discount of 0% to 54.25%. For Acthar, Mallinckrodt charged IUOE Local

542 at a discounted rate of 15% off the AWP, as set forth in the ESI PBM Agreement for all years between 2012 and the present, Mallinckrodt set the average wholesale price of Acthar used by Express Scripts for reimbursement.

83. As a result, ESI breached its agreements with IUOE Local 542 in at least two respects.

84. First, it conspired and agreed with Mallinckrodt to raise the AWP for Acthar in 2007, as set forth herein. It failed to contain the costs of Acthar, which directly and proximately caused the Acthar paid for by Plaintiff to be inflated. ESI further allowed Mallinckrodt to raise the AWPs for Acthar each year up to the years in which IUOE Local 542 beneficiaries received and paid for the drug, thereby causing further inflation in the AWPs charged by ESI to IUOE Local 542.

85. Second, it failed to return the money paid by IUOE Local 542 in the form of "rebates", as required by contract. For all years during the relevant time period, ESI agreed to pay IUOE Local 542 "100% of the rebates" it received from Mallinckrodt for Acthar. It failed to do so.

86. In the ESI PBM Agreement, "rebates" are defined as follows:

> Rebates mean retrospective rebates that are paid to ESI pursuant to the terms of a rebate contract negotiated independently by ESI with a pharmaceutical manufacturer, and directly attributable to the utilization of certain Covered Drugs by Participants. Rebates do not include Manufacturer Administrative Fees; product discounts or fees related to the procurement of prescription drug inventories by or on behalf of ESI owned and operated specialty or mail order pharmacies; fees received by ESI from manufacturers for care management or other services provided in connection with the dispensing of Specialty Products; or other fee-for-service arrangements whereby pharmaceutical manufacturers generally report the fees paid to ESI or its affiliates for services rendered as "bona fide service fees" pursuant t federal laws and regulations, including, but not limited to the Medicaid "Best Price" rule (collectively, "Other Pharma Revenue"). Such laws and regulations, as well as ESI's contracts with

> pharmaceutical manufacturers, generally prohibit ESI from sharing any such "bona fide service fees" earned by ESI, whether wholely or in part, with any ESI client. ESI represents and warrants that it will not enter into any agreement with a pharmaceutical manufacturer for Other Pharma Revenue in exchange for a reduction of Rebates.

87. ESI did not pay to IUOE Local 542 all the "rebates … directly attributable to the utilization of" the Acthar paid for by Plaintiff. It further entered into one or more agreements with Mallinckrodt for monies to paid to it that did not constitute "Other Pharma Revenue", which had the effect of reducing the rebates that would have been otherwise payable to IUOE Local 542 in the absence of such agreements.

ESI and Daraprim

88. Turing Pharmaceuticals, LLC ("Turing") acquired the rights to Daraprim and proceeded to increase the price 5000% from $13.50 to $750.00 per pill. One year's course of treatment rose from $6,500 to $361,000.

89. Strikingly, ESI employed its market power to counter Turing's action. It worked to create an alternative that was much less expensive than Daraprim.

90. On December 1, 2015, ESI announced that it would "partner with Imprimis Pharmaceuticals to drive access to a low-cost alternative to Daraprim." *See*, "ESI Champions $1 per Pill Access to an Alternative for Daraprim", December 1, 2015, at: http://lab.express-scripts.com/lab/insights/drug-options/express-scripts-champions-1-per-pill-access-to-an-alternative-for-daraprim. In partnership with ESI, "Imprimis [] offer[ed] a compounded oral formulation of pyrimethamine and leucovorin (a form of folic acid) for as low as $1 per capsule for people whose pharmacy benefit is managed by ESI." *Id.* When it is in ESI's interest, it acts to "improve access and affordability." *Id.*

91. ESI's Chief Medical Officer, Dr. Steve Miller, stated that ESI found a way to deliver "a safe, high-quality and extremely cost-effective way to provide access to a Daraprim alternative." However, because of its agreement with Mallinckrodt, ESI has *not* served as an effective agent for pharmaceutical buyers to seek to lower the cost of Acthar, or determine the availability of reasonably priced alternatives.

Acthar Pricing

92. Mallinckrodt acquired the rights to Acthar from Aventis in 2001. At acquisition, the end payor price of a vial of Acthar was approximately $40.00. After acquisition, Mallinckrodt raised the per vial, end payor price of Acthar to approximately $748.00. From 2001 until Mallinckrodt executed its new strategy in 2007, the end payor price of Acthar grew to $1,980.00.

93. When Mallinckrodt implemented its new strategy on August 27, 2007, the end payor price of Acthar rose to a staggering $27,922.80 – that is, a 1,310% increase in the span of a month, and a 69,707% increase from the time Mallinckrodt acquired the drug.

94. Until Mallinckrodt obtained FDA approval for the IS indication, the price of Acthar remained stable. However, on January 3, 2011, Mallinckrodt increased the price of Acthar 5%, another 5% on June 1, 2011, and executed a third price increase on December 27, 2011. In 2012, Acthar's end payor price was $34,150.00.

95. Near in time to Mallinckrodt plc's $5.9 billion acquisition of Questcor in 2014, the price of Acthar rose to $40,840.80. Under Mallinckrodt plc's stewardship, the end payor price of Acthar rose in 2016 to $42,942.60, and to $43,658.40 in 2017.

96. Since the acquisition of Acthar in 2001, the end payor price of Acthar has grown 109,046%, reflecting the precipitous rise in the value of the Acthar assets from $100,000 in 2001

to $5.9 billion in 2014 – a 5,899,900% increase in value. The dramatic increase in value of the Acthar assets, coupled with the durable and repeated ability to raise the price of Acthar, underscore the monopoly power wielded by Mallinckrodt in the ACTH market. Mallinckrodt's tactics described in this Complaint, however, reflect Mallinckrodt's willingness to undertake actions to maintain and grow its monopoly in the ACTH market, in violation of antitrust laws.

The Views of Express Scripts' Chief Medical Officer,
Dr. Steve Miller, on Express Scripts' Market Power

97. Beginning in 2007, Express Scripts became the exclusive agent of Mallinckrodt for the distribution of Acthar. *See* Freudenheim, *supra*. When Mallinckrodt chose to increase the price of this 50-plus year-old medication, Express Scripts did not push back. Instead, when confronted with the 2007 price increase, ESI's Chief Medical Officer Steve Miller stated that "[t]he increase was a manufacturing decision. I can't comment on it." *Id*.

98. The circumstances demonstrate why Dr. Miller chose to stay silent in the face of Express Scripts' decision to join Mallinckrodt in overcharging payors for Acthar.

99. By the time IUOE Local 542's beneficiaries were prescribed Acthar in 2015, Express Scripts was handling each and every aspect of Acthar distribution through the above-described functions. CuraScript was the exclusive specialty pharmaceutical distributor, Accredo was the specialty pharmacy provider, and UBC coordinated both the product and money flows through the ASAP Program. As Mallinckrodt's exclusive agent, Express Scripts had no interest in lowering the price for Acthar because it was making money off all aspects of its exclusive arrangement with the manufacturer. In other words, by helping Mallinckrodt maintain and enhance its monopoly power in the ACTH market, Express Scripts along with Mallinckrodt realized greater profits at the expense of payors like IUOE Local 542.

100. In the spring of 2017, ESI's Senior Vice President of Supply Chain and Specialty Pharma, Everett Neville, stated, "I don't think [Acthar is] a very great [drug] – it's a pretty poor drug with a very limited need and certainly [ESI's Chief Medical Officer, Dr,] Steve[Miller] could comment." Mr. Neville went on to say, "I think [Dr. Miller] and I both would agree, and **I think everybody in our company would agree, that [Acthar] is vastly overpriced for the value**." (emphasis added). Mr. Neville stated that he "personally told [Mallinckrodt's] management team that their drug is hugely overpriced and that he "know[s] [Dr. Miller] has as well."

101. In the same public setting, Dr. Miller stated, "[i]f you look at the data, the indications for the drug are . . . in the compendium, it's listed under a lot of indications, its real use should be very, very limited. It's an old drug. There's better products in the marketplace and so we're going to continue to be very vigilant in our utilization management."

102. Despite this express acknowledgment by ESI's Chief Medical Officer, in the weeks and months following Mallinckrodt's settlement with the FTC, Express Scripts has not acted or made any efforts to contain costs or provide a reasonable alternative for Acthar.

103. Dr. Miller has articulated the power of Express Scripts in the prescription drug marketplace to extract lower prices for its customers, using its tremendous buying power and influence. He has made all of the following public comments:

> "When I joined the company, we represented 12 million members. We're at 85 million today. That gives us extraordinary sway in the marketplace. If you think about any other aspect of health care, no one else has that many lives that they can represent." [7]

[7] *Managed Care Magazine Online*, "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma," by Peter Wehrwein, April 2015, https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

"We have tremendous scale, which allows us to get the best deals for our plan sponsors from both the pharmaceutical manufacturers and also the pharmacies. If any pharmacy chain ever becomes too large, we're able to move our patients and … get the lowest cost." [8]

"I think that because of the continued escalation of cost, you need a PBM now more than ever. And what a best-in-class PBM like Express Scripts does really ensure is great health outcomes and more affordable costs." [9]

"Pharma has shown that they feel very emboldened with their pricing power. We're using our clout in the marketplace to really tamp these down for our clients." [10]

"There are pharma companies that recognize this is in their best interest," he says. "They, like us, want to get to a sustainable marketplace. They know if they're overcharging for drugs that have very little efficacy, that puts them in a competitive disadvantage."[11]

"Discussions to control costs have never been more important, as recent estimates put global drug spend at $1.5 trillion by 2021, according to data from Quintiles IMS Holding. Yet sometimes, in the drug pricing debate, blame is placed on one part of the drug distribution system when, in fact, all of us – pharmaceutical companies, pharmacy benefit managers (PBMs), policymakers and payers – have a role to play in achieving better affordability and accessibility for medicine. As the largest PBM, our job is to make sure our patients, and our clients who provide them a pharmacy

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[8] *Business Insurance*, "Q&A: Dr. Steve Miller, Express Scripts Holding Co.," by Shelby Livingston, May 22, 2016, http://www.businessinsurance.com/article/00010101/STORY/305229991/Q&A-Dr-Steve-Miller,-Express-Scripts-Holding-Co

[9] *Managed Care Magazine Online*, "A Conversation with Steve Miller, MD: Come in and Talk With Us, Pharma," by Peter Wehrwein, April 2015, https://www.managedcaremag.com/archives/2015/4/conversation-steve-miller-md-come-and-talk-us-pharma

[10] *Nightly Business Report*, "Express Scripts Looks to Limit Drug Price Increases," by Meg Tirrell, October 2, 2015, http://nbr.com/2015/10/07/express-scripts-looks-to-limit-drug-price-increases/

[11] *Medical Marketing and Media*, "Express Scripts' Steve Miller Takes on Drug Industry in Pricing Battle," by Jaimy Lee, February 1, 2015, http://www.mmm-online.com/payersmanaged-markets/express-scripts-steve-miller-takes-on-drug-industry-in-pricing-battle/article/460559/

> benefit, are getting medicines at the lowest net cost while working with our industry partners to make that possible."[12]
>
> "…[I]t is incumbent upon the pharmacy benefits managers to more forcefully illustrate the critical role we play in making medicine more affordable and accessible. For example, we partnered with a drug maker who was willing to lower the price of its hepatitis C drug. In doing so, we were able to provide 50,000 patients affordable access to this medication."[13]
>
> "The biggest problem is not new expensive drugs but repricing old ones, and not just ones being purchased by Martin Shkreli or Valeant. You have no new research. You have no innovation. You have nothing but increased drug prices."[14]
>
> "We are constantly trying to be vigilant and chase the bad actors out of the marketplace." [15]

104. Through such statements, Express Scripts acknowledged its strong influence on pharmaceutical markets. The striking feature of the current circumstance is that Express Scripts has not asserted its influence to effectuate lower prices for Acthar.

105. While acknowledging the "value" of the medication does not warrant its high prices, Express Scripts has facilitated, rather than forestalled, Mallinckrodt's desire for ever growing profits by "repricing" an "old drug".

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[12] *Real Clear Health*, "Is Drug Pricing at an Inflection Point?" by Dr. Steve Miller, April 14, 2017, http://www.realclearhealth.com/articles/2017/04/14/is_drug_pricing_at_an_inflection_point_110550.html

[13] *Id.*

[14] *Forbes, Pharma & Healthcare*, "Solving Pharma's Shkreli Problem," by Matthew Herper, January 20, 2016, https://www.forbes.com/sites/matthewherper/2016/01/20/solving-pharmas-shkreli-problem/#6dcce78c6be3

[15] *The New York Times*, "Specialty Pharmacies Say Benefit Managers Are Squeezing Them Out," by Katie Thomas, January 9, 2017, https://www.nytimes.com/2017/01/09/business/specialty-pharmacies-say-benefit-managers-are-squeezing-them-out.html

106. With Acthar, "[y]ou have nothing but increased drug prices," due in large part to Express Scripts' decision to withhold its market power to effectuate cost containment through lower prices.

The Mallinckrodt Synacthen Acquisition

107. Since 2007, Acthar has represented 98% or more of Mallinckrodt's revenue. Acthar was so important to Questcor that its then-CEO Don Bailey told investors it "is basically a single product company."

108. Through its exorbitant price increases, Mallinckrodt was able to grow its revenue from Acthar sales from less that $1 million in 2001 to $798.9 million in 2013. Much of this increase occurred between 2011 and 2013 when Mallinckrodt's revenues increased $218.2 million to $798.9 million.

109. However, by 2013, Mallinckrodt identified a competitive threat. Novartis AG ("Novartis") developed Synacthen Depot (cosyntropin depot) ("Synacthen"), a synthetically derived ACTH medication, which, like Acthar, could be injected intra-muscularly. While it was used outside the United States, it was not yet approved by the FDA for use in the United States. Recognizing that the entry of Synacthen in the United States market for ACTH drugs would threaten its exercise of its monopoly power, Mallinckrodt first attempted to buy the rights to Synacthen in 2009. It failed.

110. As of 2013, Novartis agreed to sell Synacthen to Retrophin, Inc., which at the time was helmed by Mr. Shkreli. Mr. Shkreli founded Turing (the maker of Daraprim) after he departed Retrophin.

111. When faced with a competitive threat to its monopoly, Mallinckrodt disrupted the bidding process for Synacthen by intervening at the last minute to pay multiple times what had

been offered by three competitors, including Retrophin. Retrophin had agreed to buy Synacthen for $16 million. Upon learning of this imminent threat, Mallinckrodt acted to protect and enhance its monopoly power by licensing Synacthen for a minimum of $135 million from Novartis. It licensed the United States exclusive rights to Synacthen from Novartis, not to bring this viable synthetic alternative to Acthar to market, but to eliminate the nascent competitive threat posed by an independently owned Synacthen.

112. These actions allowed Mallinckrodt to maintain and enhance its monopoly power in the ACTH market. The Synacthen acquisition had the purpose and effect of suppressing competition and allowing Mallinckrodt to continue to raise prices for Acthar, which it did.

113. From 2013 through 2017, Mallinckrodt raised the price of Acthar from $36,144 to $43,658.

The FTC Complaint Against Mallinckrodt

114. On January 18, 2017, the Federal Trade Commission ("FTC") sued Mallinckrodt, alleging that Mallinckrodt exercised, and continues to exercise, monopoly power in the United States in the sale of Acthar. *See generally*, Complaint for Injunctive Relief and Other Equitable Relief ("FTC Complaint") at Exhibit "C" hereto.

115. The FTC alleged that such purchases "extinguished a nascent competitive threat to [Mallinckrodt's] monopoly." FTC Complaint, ¶ 1.

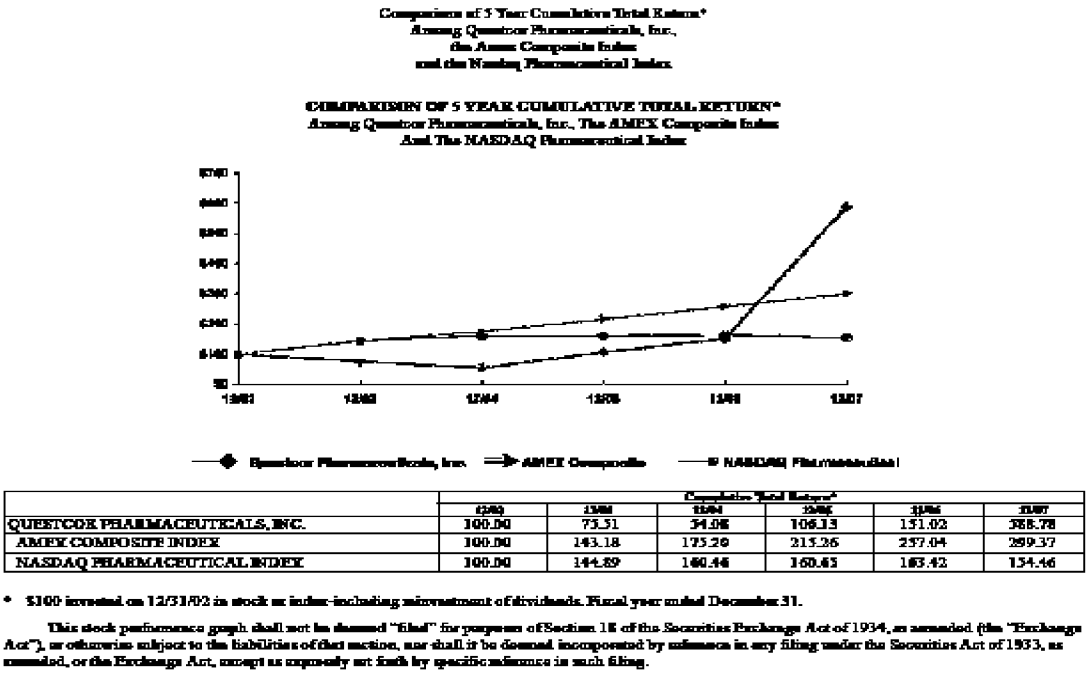
116. At all relevant times material to this case, Mallinckrodt possessed monopoly power – the ability to profitably raise price significantly above competitive levels without losing significant sales – in the relevant product market. None of the vast price increases taken by Mallinckrodt between 2007 and the present have caused a significant loss of sales. To the contrary, Mallinckrodt's sales have increased during that time.

117. Mallinckrodt has repeatedly and profitably raised Acthar's price from the time it acquired the product for $100,000 in 2001 from Aventis to the present. Mallinckrodt has been able to raise prices unchecked, as set forth above, and achieve corresponding revenue growth to more than $1 billion.

118. Mallinckrodt has encountered no competitive constraints on its ability to repeatedly increase Acthar's price and, by extension, its revenue and profit margins. Mallinckrodt does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications, except for IS.

119. Indeed, one Mallinckrodt executive commented that the price for Acthar "was chosen by looking at the prices of other specialty drugs and estimating how much insurers and employers would be willing to bear." Mallinckrodt took "some comfort that the strategy would work, and physicians would continue to use the drug, and payers would continue to pay." In fact, according to Mallinckrodt, "reality was better than expected."

120. In its Annual Report on Form 10-K for the Fiscal Year ended December 31, 2007, Questcor illustrated the effect of its monopolization strategy on its "5 Year Cumulative Total Return", illustrating a 290% return between 2006 and 2007 as follows:



	Cumulative Total Return*					
	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
QUESTCOR PHARMACEUTICALS, INC.	100.00	75.51	34.08	106.13	151.02	388.78
AMEX COMPOSITE INDEX	100.00	143.18	175.20	215.26	257.04	299.37
NASDAQ PHARMACEUTICAL INDEX	100.00	144.89	160.46	160.65	183.42	134.46

* $100 invested on 12/31/02 in stock or index-including reinvestment of dividends. Fiscal year ended December 31.

This stock performance graph shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

121. FDA approval is required to market pharmaceuticals to United States consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for United States consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

122. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

123. The United States ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's former CEO, Don Bailey, assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be

replicated in any way [by] a generic."

124. Don Bailey also claimed that one of the barriers to entry in the marketplace is the Acthar drug formulation. While Acthar is a biologic extraction of porcine pituitaries, Bailey claimed, "[i]t's an undisclosed composition, so that's a trade secret." He also claimed "[t]he manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process…The composition of Acthar that comes out of the manufacturing process is tied to the process, so if you don't know the process you can't figure out what's actually in Acthar."

125. If what the former CEO was saying was that Questcor enjoyed a natural monopoly, that does not necessarily imply the absence of market constraints. These constraints can come from a new competitive product or from a dominant buyer on the other side of the market. Both of these factors are relevant here.

Mallinckrodt Engaged in Anticompetitive Conduct
By Acquiring the Only Competitor Drug, Synacthen

126. Synacthen posed a threat to Mallinckrodt's ACTH drug monopoly, so Questcor intervened at the time when other firms were attempting to acquire the United States rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

127. Synacthen constituted a nascent competitive threat to Questcor's ACTH drug monopoly. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

128. Nevertheless, in 2007, it adopted and pursued the above-described "new strategy", consolidating Acthar distribution to just one distributor and streamlining its control over sales and distribution through the implementation of ASAP. These functions were consolidated in one significant company, Express Scripts.

129. In 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor, especially given the increasing prices Questcor was commanding for Acthar. Unsuccessful in that initial attempt, Questcor continued to monitor the competitive threat from Synacthen.

130. Then in 2012, Questcor again concluded that Synacthen posed a more immediate threat to Acthar if Synacthen was approved for sale in the United States.

131. By 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could undermine its business model.

132. On information and belief, as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Indeed, just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly

133. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

134. It is alleged that each of the three firms planned to develop Synacthen for IS and to use Synacthen to compete directly with Acthar. With this indication, each firm expected to capture a significant share of the United States ACTH market from Questcor by pricing Synacthen below Acthar's prices. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the United States ACTH market.

The Value of the Synacthen Assets

135. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation had been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

136. The asset package being sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

137. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation *de novo*, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

Questcor Disrupted the Synacthen Bidding Process

138. It is alleged that on October of 2012, Questcor learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis to develop it to compete with Questcor for the United States ACTH market. Questcor immediately reached out to

Novartis, signed a confidentiality agreement with Novartis, and submitted a confidential offer for the purchase of Synacthen.

139. Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company exchanged deal terms with Novartis and submitted formal offers. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on United States sales of Synacthen.

140. Unlike the three alternative bidders, Questcor had only incomplete plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis. Retrophin ultimately prevailed in the bidding war with a bid of $16 million.

141. However, on June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"). By the Agreements, Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor was obligated to pay a minimum of $135 million, and likely $300 million, to Novartis for Synacthen.

142. In other words, Questcor swept in at the eleventh hour to overpay—at least 8 times more than the market had determined—for the only immediate competitive threat to its monopoly for Acthar. Despite paying this amount, they did not seek FDA approval to bring the product to market.

The Lawsuit Between Retrophin and Questcor for Questcor's Antitrust Violations

143. In January 2014, Retrophin sued Questcor for antitrust violations in the United States Federal District Court for the Central District of California. *See*, *Retrophin, Inc., v. Questcor Pharmaceuticals, Inc.*, CV-14-00026-JLS (C.D.Cal) ("*Retrophin* Complaint") at Exhibit "D" hereto. To the extent relevant to Plaintiff's Complaint, the averments regarding antitrust conduct interposed by Retrophin are incorporated by reference herein.

144. In the *Retrophin* Complaint, Retrophin claimed:

> In June of 2013, plaintiff Retrophin was poised to challenge Questcor's monopoly. It had negotiated an agreement to purchase from Novartis AG ("Novartis"), the rights to sell in the US a product called Synacthen. ...
>
> Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questcor by dramatically undercutting Questcor's price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.
>
> On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In doing so, it preserved and entrenched its ACTH monopoly in the US and eliminated the competitive threat posed by Retrophin's acquisition of Synacthen. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

Retrophin Complaint, ¶¶ 4-6, at Exhibit "D".

145. The FTC apparently agreed with Retrophin's assessment.

146. The government, in its 2017 FTC complaint, mirrored Retrophin's 2014 allegations that Questcor engaged in anticompetitive conduct in violation of antitrust laws.

147. Mallinckrodt chose to settle the lawsuit with Retrophin for $15.5 million, slightly less than the $16 million Retrophin bid to purchase Synacthen from Novartis.

Mallinckrodt's Acquisition of Synacthen Harmed Competition

148. Mallinckrodt's strategy to protect its monopoly power in the market for ACTH drugs was successful. But-for Mallinckrodt's acquisition of Synacthen, one of the three alternative bidders, including Retrophin, would have acquired Synacthen and pursued its plan to develop Synacthen for IS to compete directly with Acthar at a lower price. With the acquisition of Synacthen, Mallinckrodt was able to thwart an imminent threat to its Acthar monopoly and thereby harmed competition.

149. Mallinckrodt claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the similarities between the two drugs, any therapeutic indication that Mallinckrodt was to pursue for Synacthen could easily have been pursued for Acthar.

150. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar and Synacthen.

151. However, despite its claims, Mallinckrodt has not brought Synacthen to market for any indication. Instead, it keeps Synacthen off the market to protect its monopoly power and high prices for Acthar. It took the FTC to force Mallinckrodt to release Synacthen from its hold.

Mallinckrodt settles with the FTC

152. On January 18, 2017, the FTC announced that Questcor and its parent Mallinckrodt agreed to pay $100 million to settle FTC charges that Questcor and Mallinckrodt violated antitrust laws when Questcor acquired the rights to Synacthen from Novartis in 2013.

153. According to FTC Chairwoman Edith Ramirez, "Questcor took advantage of its monopoly to repeatedly raise the prices of Acthar, from $40 in 2001 (when it acquired the rights to sell Acthar for $100,000) to more than $34,000 per vial today – an 85,000 percent increase."

154. The brunt of these monopoly prices was borne by self-funded payors, like IUOE

Local 542, located throughout the country, whose beneficiaries and patient members [had children] or [were afflicted] with [IS] or [MS] and were at the mercy of Mallinckrodt.

155. From the time it sought FDA approval for the treatment of IS, Mallinckrodt has raised the price of Acthar to over $43,000.

156. Questcor claimed that these exorbitant price increases were in response to demand. But its former Chief Executive Officer, Don Bailey, acknowledged in 2009 that "we only have about 800 patients a year. It's a very, very small – tiny – market." Consequently, the limited use of the product did not justify an over 58,000% price increase from acquisition until 2009.

157. Since the Acthar market for the treatment of IS was so limited, Questcor sought to expand its use. By 2012, Acthar was prescribed for Medicare recipients 3,387 times. To Medicare alone, this represented a cost of $141,500,000 in 2012.

158. Quantified another way, Dr. William Shaffer, a neurologist in Greeley, Colorado who was the highest prescriber of Acthar in 2012, wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare $4,000,000.

159. Acthar represented 98% or more of Questcor's sales and revenue from sales since 2007. Its manipulation of the market has resulted in a 266% increase in revenue year-over-year from 2011 to 2013. Total net sales for Questcor in 2011 were $218.2 million, $509.3 million in 2012, and $798.9 million in 2013. In each of those years, Acthar represented at least 95% of Questcor's net sales – over $1.45 billion in revenue.

160. In the words of then-CEO Don Bailey, "Questcor is basically a single-product company." But, by flexing its monopoly power, Questcor has been able to raise Acthar prices and increase revenue from Acthar in a "tiny market" from less than $1 million for fiscal year

2001 to $799 million for fiscal year 2013 – a nearly 80,000% increase. It did so in conjunction with Express Scripts.

161. Mallinckrodt's decision to exclusively contract with the agent for its largest customer to provide limited distribution for Acthar removed ESI's competitive pressure in the marketplace to cause Acthar prices to be lower. Instead, by entering into an exclusive arrangement with Express Scripts, Mallinckrodt was able to enhance its monopoly power and to raise its Acthar prices above competitive prices throughout the relevant time period from 2007 through the present.

162. The FTC forced Mallinckrodt to divest itself of the marketing rights to Synacthen in the United States. In conjunction with the announced settlement, on January 18, 2017 Mallinckrodt issued a press release explaining that, "[u]nder the agreement, Mallinckrodt will license [Synacthen] to a licensee identified by the FTC as Marathon Pharmaceuticals, LLC, to develop and pursue possible U.S. [FDA] approval of Synacthen Depot in two indications – Infantile Spasms (IS) and Nephrotic Syndrome (NS)."

163. Importantly, Mallinckrodt admitted the following about the market for ACTH products:

> Synthetic ACTH products are relatively common – Synacthen Depot and others have been on the market outside of the U.S. for years, if not decades – and in Mallinckrodt's view are not especially complex to either formulate or manufacture at scale. However, history has borne out the FTC's view that there are "high barriers to entry" for a synthetic ACTH in the U.S. market. Synacthen Depot has never been FDA-approved for use in the U.S. In fact, in all the time it has been commercially available, no owner (including the owner prior to Questcor) ever undertook U.S. development in any indication until after the Questcor acquisition when Mallinckrodt began preparation for development in DMD (Duchenne Muscular Dystrophy).

164. In July, 2017, The FTC announced that it had approved a sublicense submitted by Mallinckrodt "granting West Therapeutic Development, LLC certain rights to develop and market" Synacthen. The FTC explained, "[u]nder the January [settlement] order, the FTC approved Marathon Pharmaceuticals, LLC as the sublicensee. Marathon has since spun off the assets and personnel related to the development of a synthetic ACTH drug to West Therapeutic Development, LLC."

165. In its own press release, Mallinckrodt noted that it retained the rights to "continue to develop the product for all ***other*** indications in the U.S.", beyond IS and NS (emphasis in original). "Mallinckrodt is doing so under the development name MNK-1411 and has filed an Investigational New Drug (IND) application with the FDA to assess the drug's potential in the treatment" of other diseases. "The company completed a phase 1 study for MNK-1411…", and expected a "phase 2 trial" later in 2017. Mallinckrodt pointed out that the "FDA has granted Mallinckrodt's request for a Fast Track designation for its IND application", demonstrating that both Questcor and Mallinckrodt could have done so long before 2017.

COUNT I
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
ALL DEFENDANTS
Pennsylvania Unfair Trade Practices and Consumer Protection Law

166. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

167. Pennsylvania's Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. §§201, et seq. ("UTPCPL") makes unlawful any "unfair methods of competition" and "unfair or deceptive acts or practices", including the following, among others:

> (ii) Causing likelihood of confusion or of misunderstanding as to the source, sponsorship, approval or certification of goods or services;

(v) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have;

(vii) Representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another;

(viii) Disparaging the goods, services or business of another by false or misleading representation of fact;

(xi) Making false or misleading statements of fact concerning the reasons for, existence of, or amounts of price reductions; and

(xxi) Engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or of misunderstanding.

168. The unfair methods of competition, and unfair or deceptive acts or practices, in the conduct of any trade or commerce as defined above are declared unlawful under the UTPCPL.

169. The UTPCPL authorizes any person, including natural persons, corporations, trusts, partnerships, incorporated and unincorporated associations, and any other legal entities to seek an injunction, damages, costs, and reasonable attorneys fees to prevent and ameliorate the anticompetitive conducted described herein.

170. IUOE Local 542 is a person pursuant to the UTPCPL. IUOE Local 542 has been injured as a result of the Defendants' conduct in violation of Pennsylvania law, and hereby seeks damages.

171. The acts and practices described herein demonstrate that Mallinckrodt and Express Scripts acted unlawfully within the meaning of the UTPCPL such that IUOE Local 542 may be awarded up to three times the actual damages sustained, and such additional relief as deemed necessary or proper.

172. IUOE Local 542 seeks relief against Mallinckrodt and Express Scripts for their scheme to fix the price of Acthar at supra-competitive levels and maintain Mallinckrodt's monopoly power.

173. Mallinckrodt and Express Scripts created restrictions on trade and commerce through the creation of the exclusive arrangement for Acthar.

174. Mallinckrodt and Express Scripts agreed to raise the prices of Acthar.

175. As described herein, Mallinckrodt and Express Scripts agreed to maintain the supra-competitive prices of Acthar through the ASAP Program, limiting distribution of the drug and stifling the ability of a competitor to enter the ACTH market. Further, to maintain these supra-competitive prices, Mallinckrodt acquired Synacthen and refused to bring it to market, despite its demonstrated capability to do so. This conduct caused IUOE Local 542 to pay prices for Acthar significantly greater than in a competitive market. Therefore, IUOE Local 542 is entitled to relief under the UTPCPL.

176. IUOE Local 542 was injured as a direct result of the Defendants' conduct in violation of Pennsylvania law and hereby seeks damages.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT II
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
ALL DEFENDANTS
Negligent Misrepresentation

177. Plaintiff hereby incorporates by reference the preceding and following averments

as if fully set forth herein and further alleges as follows.

178. Defendants' acts violate Pennsylvania common law against negligent misrepresentation.

179. In setting the AWP-based prices for Acthar, upon which prices the amounts paid by IUOE Local 542 were based, the Defendants made material misrepresentations that those prices represented a calculation of real and fact-based prices for their drugs, and that they represented the actual value of the product in the marketplace.

180. These representations were material to the transactions at hand in that IUOE Local 542 used and relied upon these prices as the basis for the amount to pay and/or reimburse for Acthar.

181. As set forth more fully above, these prices were artificial prices, unrelated to any actual, reasonable price in the marketplace, or actual value of Acthar, but created and manipulated by the Defendants for the purpose of generating exorbitant revenue, thus constituting false representations which the Defendants knew or, in the absence of recklessness, should have known to be false.

182. The Defendants made these false representations about the actual prices for and value of Acthar with the intent of misleading IUOE Local 542 into relying on the prices as real and fact-based prices, rather than artificially inflated prices.

183. IUOE Local 542 justifiably relied upon these false misrepresentations in purchasing and/or reimbursing Acthar at the amount charged by Express Scripts based on the price set by Mallinckrodt.

184. IUOE Local 542's contracts with Express Scripts provided for "cost containment" and for discounted prices for specialty drugs at varying rates, intended to reflect the efforts of

Express Scripts to provide cost containment. The prices for Acthar set forth in such contracts were prices set by Mallinckrodt and set forth by Express Scripts in its contracts. As such, all Defendants communicated these false prices directly to IUOE Local 542 for the Acthar sold.

185. As a direct and proximate result of the false representations of the Defendants, as set forth above, IUOE Local 542 was harmed in that it was unaware of the artificial, inflated prices of Acthar, would not have paid and/or reimbursed the artificially inflated prices for Acthar had it known of the false representations and, in fact, overpaid for the Acthar because of the false representations.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT III
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
ALL DEFENDANTS
Aiding and Abetting

186. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

187. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff, and continuing thereafter until the present, Defendants and other unnamed co-conspirators, between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to defraud and deceive the Plaintiff by causing it to pay more for Acthar than it otherwise would have paid in the absence of the Defendants' conspiracy and concerted action.

188. Pursuant to the unfair and deceptive scheme to distribute, market and sell Acthar to derive substantial profits, and the conspiracy alleged herein, and in furtherance thereof, Defendants and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to deceive IUOE Local 542, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

a. discussing and agreeing among themselves and with their co-conspirators that they would directly control the price at which IUOE Local 542 paid for Acthar;

b. discussing and agreeing among themselves and with their co-conspirators that they would increase the price at which IUOE Local 542 paid for Acthar;

c. discussing and agreeing among themselves and with their co-conspirators that they would directly control the ASAP program materials and website which enrolled patients into an exclusive distribution network for the administration of Acthar, allowing Defendants to conduct their unfair pricing scheme for Acthar;

d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through the ASAP Program;

e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP Program through the marketing alleged herein, and through use of the mail and the wires;

f. discussing and agreeing among themselves and with their co-conspirators that they would participate in the affairs of the ASAP program by using a fraudulent scheme to market and sell Acthar at inflated prices; and

g. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about the Acthar inflated prices, the monies earned from payors like IUOE Local 542, and their exclusive arrangement to maintain and enhance Mallinckrodt's monopoly power as alleged herein.

189. In addition to the specific facts set forth above, it is alleged the Defendants and their co-conspirators engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the direct distribution, marketing, sale and administration of Acthar to payors like IUOE Local 542, and deriving substantial profits from these activities.

190. The Defendants performed the conspiratorial acts set forth herein intending to injure payors of Acthar, like IUOE Local 542, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

191. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to IUOE Local 542, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences.

192. As a direct and proximate result of the Defendants' conspiracy as alleged herein, IUOE Local 542 has been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Defendants, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT IV
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
EXPRESS SCRIPTS
Unjust Enrichment

193. Plaintiff hereby incorporates by reference the preceding and following averments

as if fully set forth herein and further alleges as follows.

194. This Count alleges unjust enrichment against Express Scripts.

195. IUOE Local 542 agreed to retain Express Scripts' services exclusively and in good faith and in reasonable reliance on Express Scripts' conduct and representations described herein.

196. Among other things, IUOE Local 542 at all times had a reasonable expectation that Express Scripts' conduct would result in affordable services, including "cost containment" for specialty drugs like Acthar.

197. IUOE Local 542 and its beneficiaries made direct payments to Express Scripts which were valuable to Express Scripts, and Express Scripts was unjustly enriched by such direct payments, in that, the reimbursement rates charged by Express Scripts at extremely high prices with inequitable discounts were valuable and beneficial to Express Scripts.

198. By engaging in the conduct described herein, Express Scripts has knowingly obtained benefits from IUOE Local 542, namely grossly inflated revenue from its direct involvement in coordinating all aspects of IUOE Local 542's receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Express Scripts to retain such benefits.

199. By engaging in the unlawful conduct described herein, Express Scripts has been knowingly enriched by the amount charged for Acthar over and above what it could have charged in a competitive market, wherein Express Scripts would use its market power to extract lower prices from Mallinckrodt in fulfillment of its obligation to contain costs, and what it could have charged if it had engaged in appropriate cost containment measures.

200. By assisting Mallinckrodt in maintaining and enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade, and engaging in other unlawful acts and practices, Express Scripts was able to extract exorbitant revenue from IUOE Local 542 beyond what it could have received in the absence of such unlawful conduct. This conduct violated state consumer fraud and antitrust laws, as well as the common law of Pennsylvania, and as such, interfered with the legally protected interests of IUOE Local 542.

201. IUOE Local 542 is therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT V
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
MALLINCKRODT
Unjust Enrichment

202. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

203. This Count alleges unjust enrichment against Mallinckrodt.

204. IUOE Local 542's covered beneficiaries received direct shipments of Acthar from Mallinckrodt via its exclusive distribution mechanism established with Express Scripts. In exchange for such Acthar, IUOE Local 542 made direct payments to Express Scripts for the benefit of Mallinckrodt. Indeed, such payments were transferred by Express Scripts to

Mallinckrodt pursuant to an understanding between the two that the total amount would be forwarded to Mallinckrodt, less a certain amount previously agreed to by Mallinckrodt and Express Scripts. The amount charged by Mallinckrodt for Acthar was the amount paid by Local 542 pursuant to its agreement with Express Scripts.

205. The amounts paid by IUOE Local 542 were valuable to Mallinckrodt and Mallinckrodt was unjustly enriched by such direct payments, in that, the reimbursement rates charged by Mallinckrodt at extremely high prices with inequitable discounts were valuable and beneficial to Express Scripts.

206. By engaging in the conduct described herein, Mallinckrodt has knowingly obtained benefits from IUOE Local 542, namely, grossly inflated revenue from its direct involvement in coordinating all aspects of IUOE Local 542's receipt of and payments for Acthar, under circumstances such that it would be inequitable and unjust for Mallinckrodt to retain such benefits.

207. By engaging in the unlawful conduct described herein, Mallinckrodt has been knowingly enriched by the amount charged for Acthar over and above what it could have charged in a competitive market, wherein Express Scripts would have used its market power to extract lower prices from Mallinckrodt in fulfillment of its obligation to contain costs, and what it could have charged if it had engaged in appropriate cost containment measures.

208. Mallinckrodt, by working with Express Scripts in maintaining and enhancing its monopoly, and its exercise of monopoly power through increasing prices over a decade, and engaging in other unlawful acts and practices, Mallinckrodt was able to extract exorbitant revenue from IUOE Local 542 beyond what it could have received in the absence of such unlawful conduct. This conduct violated state consumer fraud and antitrust laws, as well as the

common law of Pennsylvania, and, as such, interfered with the legally protected interests of IUOE Local 542.

209. IUOE Local 542 is therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Mallinckrodt, in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VI
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
EXPRESS SCRIPTS
Breach of Contract
Breach of the ESI PBM Agreement

210. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

211. This Count alleges breach of the ESI PBM Agreement against Express Scripts.

212. By its representations, manifestations of assent, customs and practices, ESI is bound to and by the terms of the ESI PBM Agreement.

213. By the foregoing conduct, specifically ESI's failure to provide "cost containment" services either through nonfeasance or malfeasance, ESI breached the ESI PBM Agreement, repudiated its obligations under the ESI PBM Agreement, and is in default of the ESI PBM Agreement. Specifically, ESI agreed with Mallinckrodt to inflate the AWPs for Acthar in violation of the letter and spirit of the contract. ESI also diverted monies from Plaintiff that should have been paid as rebates.

214. IUOE Local 542 performed and met all of its obligations under the ESI PBM Agreement to date and has a right to and is entitled to all remedies ascribed to it under the ESI PBM Agreement and Pennsylvania law.

215. IUOE Local 542 has been damaged as a direct and proximate result of ESI's failure to perform under the terms of the ESI PBM Agreement.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VII
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
EXPRESS SCRIPTS
Promissory Estoppel

216. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein.

217. This Count alleges promissory estoppel against Express Scripts. It charges that ESI's conduct described above constitutes a promise to perform under the terms of the ESI PBM Agreement, and a promise upon which IUOE Local 542 relied upon to its detriment.

218. IUOE Local 542 seeks enforcement of ESI's promise to continue with ESI's obligations under the ESI PBM Agreement.

219. ESI utterly refused and failed to fulfill its representations and promises concerning the terms and obligations under the ESI PBM Agreement, including the promise of cost containment with respect to Acthar.

220. IUOE Local 542 relied on the conduct described above, and in justifiable reliance thereon, and as a direct and proximate result of its reliance thereon, IUOE Local 542 has been damaged.

221. Injustice can be avoided only by enforcing ESI's representations and promises concerning the expectations that it created regarding ESI's obligations under the ESI PBM Agreement, and awarding IUOE Local 542 damages based on ESI's failure to fulfill its representations and promises.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

COUNT VIII
INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 542
v.
EXPRESS SCRIPTS
Breach of the Implied Covenant of Good Faith and Fair Dealing

222. Plaintiff hereby incorporates by reference the preceding and following averments as if fully set forth herein and further alleges as follows.

223. The general duty of good faith and fair dealing in the performance of a contract is found in the Restatement (Second) of Contracts, Section 205, which provides that "every contract imposes upon each party a duty of good faith and fair dealing in its performance and its enforcement."

224. In Pennsylvania and other states, the duty of good faith is defined as honesty in fact in the conduct or transaction concerned.

225. The duty to perform contractual obligations in good faith applies to the ESI PBM Agreement and requires ESI to use its best efforts to fulfill its promise to provide "cost containment" services.

226. By failing to provide "cost containment" for Acthar as set forth herein, specifically agreeing with Mallinckrodt to raise the AWPs for Acthar and agreeing with Mallinckrodt to pay ESI monies that should have been paid as rebates, ESI breached the covenant of good faith and fair dealing.

227. ESI's breach of the covenant of good faith and fair dealing was the direct and proximate result of injury and damages to IUOE Local 542.

WHEREFORE, International Union of Operating Engineers Local 542 demands that judgment be entered in its favor and against Express Scripts in an amount to be determined at trial, including but not limited to costs, attorneys' fees, and such other relief deemed just and appropriate by this Court.

PRAYER FOR RELIEF

WHEREFORE, International Union of Operating Engineers Local 542 requests the Court to enter the following relief:

a. Declare unlawful the acts and practices alleged herein, enjoin the Defendants from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;

b. Enter judgment against all Defendants for the violations alleged herein;

c. Award the actual damages incurred by Plaintiff as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;

d. Award statutory damages set forth herein under the statutory claims alleged;

e. Award treble damages or multiple damages by operation of law;

f. Award punitive damages;

g. Award Plaintiff the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and

h. Award such other and further relief as the Court may deem just and appropriate.

JURY DEMAND

Plaintiff demands a trial by jury of all issues so triable in this cause.

Respectfully submitted,

Dated: May 25, 2018

By: *s/ Donald E. Haviland, Jr.*

Donald E. Haviland, Jr.
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Phone: (215) 609-4661
Fax: (215) 392-4400

Counsel for Plaintiff, International Union of Operating Engineers Local 542

VERIFICATION

I, John Heenan, hereby verify that I am the Administrator to the International Union of Operating Engineers Local No. 542, that I am authorized to make this Verification and that the facts set forth in the foregoing Complaint are true and correct to the best of my knowledge, information and belief. I understand that this Verification is made subject to the penalties of 18 Pa.C.S.A. §4904 relating to unsworn falsification to authorities.

Dated: 5/24/18

John Heenan

John Heenan, Administrator

EXHIBIT A

H.P. Acthar® GEL
(repository corticotropin injection) 80 U/mL

FAX: 1-877-937-2284

Acthar Start Form
Please complete Start Form and fax toll-free
TEL: 1-888-435-2284
Monday through Friday (8:00 am to 9:00 pm EST)
Saturday (9:00 am to 2:00 pm)

1. PATIENT INFORMATION
Patient has been notified of referral ☐ YES ☐ NO

PATIENT FIRST NAME | PATIENT MIDDLE INITIAL | PATIENT LAST NAME | DATE OF BIRTH | GENDER

HOME ADDRESS | CITY | STATE | ZIP

SHIPPING ADDRESS (IF NOT HOME ADDRESS) | CARE OF (IF NOT ADDRESSED TO PATIENT) | CITY | STATE | ZIP

HOME PHONE | MOBILE | OK TO TEXT | BEST TIME TO CALL | PREFERRED LANGUAGE IF NOT ENGLISH

EMAIL ADDRESS | PATIENT REPRESENTATIVE | RELATIONSHIP | TELEPHONE

2. INSURANCE INFORMATION (PLEASE INCLUDE COPIES OF CARDS)

PHARMACY BENEFITS | SUBSCRIBER ID # | GROUP # | TEL #

PRIMARY MEDICAL INSURANCE | POLICY HOLDER | RELATIONSHIP | SUBSCRIBER ID # | GROUP # | TEL #

3. HEALTHCARE PROVIDER (HCP) INFORMATION

HCP FIRST NAME | HCP LAST NAME | HCP MIDDLE INITIAL | NPI # | GROUP NPI # (IF APPLICABLE) | STATE LICENSE #

SPECIALTY: ☐ NEPHROLOGY ☐ NEUROLOGY ☐ PULMONOLOGY ☐ RHEUMATOLOGY ☐ OPHTHALMOLOGY ☐ OTHER _____ IF OTHER PLEASE INDICATE

FACILITY NAME | TELEPHONE | FAX

ADDRESS | CITY | STATE | ZIP

OFFICE CONTACT NAME | CONTACT TELEPHONE | EMAIL ADDRESS | PREFERRED METHOD OF COMMUNICATION

4. PRESCRIPTION: H.P. ACTHAR® GEL
NDC# 63004-8710-1 5 mL multidose vial containing 80 USP units per mL

PRIMARY DIAGNOSIS: _____ **ICD-10:** _____

INITIATE PATIENT WITH:

DOSE: _____ ☐ UNITS ☐ ML **SCHEDULE/FREQUENCY:** _____

QUANTITY OF 5 ML MULTIDOSE VIALS: _____ **REFILLS:** _____

ROUTE OF ADMINISTRATION: ☐ INTRAMUSCULAR ☐ SUBCUTANEOUS

ADDITIONAL SPECIAL INSTRUCTIONS, OR TAPER DOSE, IF APPLICABLE: _____

ALLERGIES: _____

SUPPLIES:

SYRINGE SIZE: ☐ 1 mL ☐ 3 mL ☐ Other size ____ **QUANTITY:** ____ **NEEDLE SIZE:** ☐ 20 g needle, 1 inch ☐ 23 g needle, 1 inch ☐ 25 g needle, 1 inch ☐ 25 g needle, 5/8 inch Subcutaneous only ☐ (other): ____ **QUANTITY:** ____

PATIENT WEIGHT (FOR WEIGHT-BASED DOSING ONLY): _____ **SUPPLY REFILLS:** ____ **SHARPS CONTAINER:** _____ **OTHER SUPPLIES:** _____

HOME INJECTION TRAINING SERVICES (HITS)

By initialing here (original required) I request that company-funded HITS services be arranged for my patient. I understand that HITS is for one instruction visit only and NOT a home health nursing service. I also understand that all reasonable efforts will be made to schedule the HITS training visit within 24 hours of the patient's receipt of drug shipment.

_____
INITIALS DATE

5. PRESCRIPTION, CONSENT AND STATEMENT OF MEDICAL NECESSITY: HCP SIGNATURE REQUIRED

I certify that H.P. Acthar® Gel is medically necessary for this patient and that I have reviewed this therapy with the patient and will be monitoring the patient's treatment. I verify that the patient and healthcare provider information on this enrollment form is complete and accurate to the best of my knowledge. I understand that I must comply with my practicing state's specific prescription requirements such as, e-prescribing, state specific prescription form, fax language, etc. Non-compliance of state specific requirements could result in outreach to me by the dispensing pharmacy.

I authorize United BioSource Corporation ("UBC"), the current operator of the Acthar Support and Access Program ("Program"), and other designated operators of the Program, to perform a preliminary assessment of benefit verification for this patient and furnish information requested by the patient's insurer that is available on this form. I understand that insurance verification is ultimately the responsibility of the provider and third-party reimbursement is affected by a variety of factors. While UBC tries to provide accurate information, they and Mallinckrodt make no representations or warranties as to the accuracy of the information provided.

I understand that representatives from the Program or UBC may contact me or my patient for additional information relating to this prescription. I acknowledge and agree that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy.

HCP Prescriber Signature - Please sign ONE LINE below

_____ _____
DISPENSE AS WRITTEN DATE SUBSTITUTIONS ALLOWED DATE

Prescriber signature required to consent and validate prescriptions. Prescriber attests that this is her/his signature. NO STAMPS. By signing, I certify that the above is medically necessary.

For Patient:_____ **DOB:**_____

6. DIAGNOSIS AND MEDICAL INFORMATION

Diagnosis

Please select diagnosis and responses to associated questions

Ankylosing spondylitis

Dermatomyositis

Infantile spasms

Has diagnosis been confirmed by EEG?

❑ YES ❑ NO

Patient's weight: _____

Requested drug delivery date: _____

Multiple sclerosis

Is Acthar to be used to treat an acute exacerbation?

❑ Exacerbation ❑ Other_____ Must check one

Onset of acute exacerbation Date:_____

Optic neuritis

Polymyositis

Proteinuria in nephrotic syndrome

Please indicate etiology:

Focal segmental glomerular sclerosis (FSGS)

IgA nephropathy (IgAN)

Lupus nephritis

Membranous nephropathy (MN)

Other: _____

Psoriatic arthritis

Rheumatoid arthritis

Sarcoidosis

Systemic lupus erythematosus

Is Acthar to be used to treat an acute exacerbation?

❑ YES ❑ NO Must check one

Lupus nephritis?

❑ YES ❑ NO

Uveitis

Other diagnosis _____

7. HISTORY OF CORTICOSTEROID USE (IF APPLICABLE) PLEASE ADD DETAILS IN SECTION 8 BELOW

Please check all that apply

A corticosteroid was tried with the following response(s):

Corticosteroid use failed, but same response not expected with Acthar

Patient hypersensitive or allergic to corticosteroids

Patient intolerant to corticosteroids

Other: _____

OR

A corticosteroid was not tried due to the following response(s):

Corticosteroid use is contraindicated for this patient

Intravenous access is not possible for this patient

Patient has known intolerance to corticosteroids

Other:_____

8. CONCURRENT MEDICATIONS

9. RELEVANT TREATMENT HISTORY (INCLUDING RECENT STEROID HISTORY)

Therapy Name	Dose	Start Date	Stop Date (if applicable)	Explain Outcome With Detail (ex. type of outcome)

(Attach additional pages as necessary)

OTHER RELEVANT CLINICAL INFORMATION

HCP SIGNATURE: REQUIRED FOR DOCUMENTATION

NAME SIGNATURE DATE

H.P. Acthar® GEL
(repository corticotropin injection) 80 U/mL

For completion by patient or their representative

Patient Name:_____ **DOB:**_____

10. PATIENT AUTHORIZATION(S)

For Patient Review and Completion. If patient is not available, authorization will be obtained from patient by Acthar Support and Access Team upon receipt of referral.

By signing this authorization, I authorize my physician(s), my health insurance company, my pharmacy providers and Mallinckrodt ARD Inc., the distributor of Acthar ("Mallinckrodt"), and its agents, authorized designees and contractors, including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support and Access Program on behalf of Mallinckrodt (collectively, "Designated Parties"), to use and disclose to other Designated Parties health information relating to my medical condition, treatment, and insurance coverage (my "Health Information") in order for them to (1) provide certain services to me, including reimbursement and coverage support, patient assistance and access programs, medication shipment tracking, and home injection training, (2) provide me with support services and information associated with my Acthar therapy, (3) for internal business purposes, such as for marketing research, internal financial reporting and operational purposes, and (4) to carry out the Designated Parties' respective legal responsibilities.

Once my Health Information has been disclosed to the Designated Parties, I understand that it may be re-disclosed by them and no longer protected by federal and state privacy laws. However, the Designated Parties agree to protect my Health Information by using and disclosing it only for the purposes detailed in this authorization or as permitted or required by law.

I understand that I may refuse to sign this authorization and that my physician and pharmacy will not condition my treatment on my agreement to sign this authorization form, and my health plan or health insurance company will not condition payment for my treatment, insurance enrollment or eligibility for insurance benefits on my agreement to sign this authorization form. I understand that my pharmacies and other Designated Parties may receive payment in connection with the disclosure of my Health Information as provided in this authorization. I understand that I am entitled to receive a copy of this authorization after I sign it.

I may revoke (withdraw) this authorization at any time by mailing a letter to Acthar Support and Access, 255 Technology Park, Lake Mary, FL 32746. Revoking this authorization will end further disclosure of my Health Information to Designated Parties by my pharmacy, physicians and health insurance company when they receive a copy of the revocation, but it will not apply to information they have already disclosed to the Designated Parties based on this authorization. I also know I may cancel my enrollment in a patient support program at any time in writing by contacting Mallinckrodt via fax at 877-937-2284.

This authorization is in effect for 1 year or until the conclusion of any ongoing coverage support, whichever is longer, once I have signed it unless I cancel it before then.

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE

I authorize Mallinckrodt and its agents to receive, use, and disclose my health information relating to my medical condition, treatment, insurance coverage, and contact information from me, my healthcare providers, my pharmacies, and my health insurance company in order to (1) contact me about participation in Acthar patient programs, (2) provide me with educational or other informational materials, (3) administer its education and other patient-related programs, (4) conduct surveys that request my feedback, and (5) for Mallinckrodt to carry out its legal responsibilities in connection with these education and support programs. I agree to let Mallinckrodt or its agents contact me in the future about these offerings. Once my health information has been disclosed to the education, informational and/or support program I choose to participate in, I understand that it may be redisclosed by Mallinckrodt or its agents, and they are authorized to use or disclose this information in the manner described here and as permitted by this authorization or as otherwise permitted or required by law, and that federal and state privacy laws may no longer protect the information. However, Mallinckrodt and its agents agree to protect my health information by using and disclosing it only for the purposes described in this authorization or as permitted or required by law. This authorization will remain in effect until I cancel it which I may do so at any time by contacting Mallinckrodt via fax at 877-937-2284. Cancelling this authorization will end further use or disclosure of my health information by Mallinckrodt or its agents (except to the extent that such parties took actions based on this authorization prior to my revocation). If I withdraw my permission, I know that this means I may no longer receive information on supplemental education or support programs. Once I withdraw my permission, no new information will be disclosed to Mallinckrodt or its agents, but Mallinckrodt and its agents may continue to use the information that was collected before I withdrew my permission as permitted by this authorization or as otherwise permitted or required by law. I may request a copy of this signed authorization.

PATIENT NAME OR LEGAL REPRESENTATIVE	PATIENT SIGNATURE	IF LEGAL REPRESENTATIVE, RELATIONSHIP TO PATIENT	DATE

Acthar Support and Access Program
FAX: 1-877-937-2284 TEL: 1-888-435-2284

INDICATIONS AND USAGE

- **Infantile spasms:** H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age
- **Multiple Sclerosis:** H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease
- **Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), ankylosing spondylitis
- **Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis)
- **Dermatologic Diseases:** Severe erythema multiforme, Stevens-Johnson syndrome
- **Allergic States:** Serum sickness
- **Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation
- **Respiratory Diseases:** Symptomatic sarcoidosis
- **Edematous State:** To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- Acthar should never be administered intravenously
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of Acthar
- Acthar is contraindicated where congenital infections are suspected in infants
- Acthar is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origins

WARNINGS AND PRECAUTIONS

- The adverse effects of Acthar are related primarily to its steroidogenic effects
- Acthar may increase susceptibility to new infection or reactivation of latent infections
- Suppression of the hypothalamic-pituitary-axis (HPA) may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Adrenal insufficiency may be minimized by tapering of the dose when discontinuing treatment. During recovery of the adrenal gland patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids. Monitor patients for effects of HPA suppression after stopping treatment
- Cushing's Syndrome may occur during therapy but generally resolves after therapy is stopped. Monitor patients for signs and symptoms
- Acthar can cause elevation of blood pressure, salt and water retention, and hypokalemia. Blood pressure, sodium and potassium levels may need to be monitored
- Acthar often acts by masking symptoms of other diseases/disorders. Monitor patients carefully during and for a period following discontinuation of therapy
- Acthar can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Monitor for signs of bleeding
- Acthar may be associated with central nervous system effects ranging from euphoria, insomnia, irritability, mood swings, personality changes, and severe depression, and psychosis. Existing conditions may be aggravated
- Patients with comorbid disease may have that disease worsened. Caution should be used when prescribing Acthar in patients with diabetes and myasthenia gravis
- Prolonged use of Acthar may produce cataracts, glaucoma and secondary ocular infections. Monitor for signs and symptoms
- Acthar is immunogenic and prolonged administration of Acthar may increase the risk of hypersensitivity reactions. Neutralizing antibodies with chronic administration may lead to loss of endogenous ACTH activity
- There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver
- Long-term use may have negative effects on growth and physical development in children. Monitor pediatric patients
- Decrease in bone density may occur. Bone density should be monitored for patients on long-term therapy
- Pregnancy Class C: Acthar has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

ADVERSE REACTIONS

- Common adverse reactions for Acthar are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain
- Specific adverse reactions reported in IS clinical trials in infants and children under 2 years of age included: infection, hypertension, irritability, Cushingoid symptoms, constipation, diarrhea, vomiting, pyrexia, weight gain, increased appetite, decreased appetite, nasal congestion, acne, rash, and cardiac hypertrophy. Convulsions were also reported, but these may actually be occurring because some IS patients progress to other forms of seizures and IS sometimes mask other seizures, which become visible once the clinical spasms from IS resolve

Other adverse events reported are included in the full Prescribing Information.

Please see accompanying full Prescribing Information.

Mallinckrodt Pharmaceuticals

EXHIBIT B

QUESTCOR

URGENT PRODUCT ALERT
H.P. Acthar® Gel

July 2, 2007

Dear Healthcare Professional,

As you know, H.P. Acthar® Gel (repository corticotropin injection) plays a critical role in many inpatient and outpatient treatment regimens. **Effective August 1, 2007, Acthar Gel (NDC # 63004-7731-1) will be available exclusively through Specialty Pharmacy Distribution.** Acthar Gel will no longer be available from traditional pharmaceutical wholesalers or retail pharmacies. Please be sure to share this information appropriately with your staff and patients.

For Hospital Stock Orders

Beginning July 16, 2007, hospitals should place all stock orders with CuraScript Specialty Distribution **(877-599-7748)**. We suggest that appropriate personnel at your facility contact CuraScript Specialty Distribution **(877-599-7748)** as soon as possible to establish an account.

Planning for Patient Discharge – Outpatient Prescriptions

Beginning July 16, 2007, when treatment with Acthar Gel is initiated in a hospital setting with the intent to continue after discharge, it is imperative that the outpatient prescription order be placed immediately after treatment initiation to ensure an uninterrupted supply of Acthar Gel at discharge. Beginning July 16, 2007, please contact the following support and access program to get prescriptions filled and for assistance with reimbursement:

Acthar Support & Access Program (ASAP)
- **PHONE: 888-435-2284**
- **FAX: 877-937-2284**

More information and referral forms can be obtained at **www.acthar.com.**

Filling Prescriptions

Please tell your patients currently having Acthar Gel prescriptions filled at retail pharmacies to immediately confirm the pharmacy has stock on hand for their remaining refills. Beginning July 16, 2007, all new Acthar Gel prescriptions should be submitted to the Acthar Support & Access Program **(PHONE: 888-435-2284; FAX: 877-937-2284).**

Questcor is committed to providing uninterrupted availability of Acthar Gel for patients who critically need it. This change in Acthar Gel distribution and the creation of the Acthar Support & Access Program is an important part of this mission.

Sincerely,

Steve Cartt, Executive Vice President, Corporate Development
Questcor Pharmaceuticals

EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

FEDERAL TRADE COMMISSION, the States of ALASKA, MARYLAND, NEW YORK, TEXAS, and WASHINGTON, Plaintiffs, v. MALLINCKRODT ARD INC., formerly known as QUESTCOR PHARMACEUTICALS, INC., a California corporation, and MALLINCKRODT PLC, an Irish public limited company, Defendants.	Case Number:

COMPLAINT FOR INJUNCTIVE AND OTHER EQUITABLE RELIEF

Plaintiffs, the Federal Trade Commission ("FTC") and the states of Alaska, Maryland, New York, Texas, and Washington (collectively, the "Plaintiff States"), by their designated attorneys, petition this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, and the relevant state laws—Alaska Stat. §§ 45.50.501, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080—for permanent injunctive and other equitable relief against Defendants Mallinckrodt ARD Inc., formerly known as Questcor Pharmaceuticals, Inc. ("Questcor"), and Mallinckrodt plc ("Mallinckrodt") to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and acts of monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2, and various state laws as identified in Count III, and state for their complaint as follows:

I. Nature of the Case

1. Through its anticompetitive conduct, Questcor has extinguished a nascent competitive threat to its monopoly. Questcor's H.P. Acthar Gel ("Acthar") is the only therapeutic adrenocorticotropic hormone ("ACTH") product sold in the United States. ACTH is the standard of care for infantile spasms ("IS"), a rare but extremely serious disorder involving seizures within the first two years of life. It is also used to treat nephrotic syndrome ("NS")—a kidney disorder whose largest single cause is idiopathic membranous nephropathy ("IMN")—as well as other disorders.

2. Questcor acquired Acthar from Aventis Pharmaceuticals, Inc. in 2001 for $100,000 plus modest royalties. At that time, the price of Acthar was $40 per vial. Questcor has since raised Acthar's price to over $34,000 per vial—an 85,000% increase.

3. A course of Acthar treatment for IS requires multiple vials and can cost well over $100,000.

4. For other indications, as the CEO of Mallinckrodt has admitted, Acthar is in many cases "the only alternative for patients that have tried and failed on many other therapies."

5. Questcor's Acthar price increases have persisted and proved very profitable. Acthar's U.S. revenues in 2015 exceeded $1 billion.

6. In Europe, Canada, and other parts of the world, doctors treat patients suffering from these same conditions with Synacthen Depot ("Synacthen"), a synthetic ACTH drug. Although Acthar is a natural ACTH drug derived from the pituitary glands of pigs, Acthar and Synacthen have very similar biological activities and pharmacological effects. As the Canadian product monograph for Synacthen reads, "SYNACTHEN . . . exhibits the same activity as natural ACTH with regard to all its biological activities." Questcor considers the drugs so

similar that it submitted Synacthen information to support its application to the U.S. Food and Drug Administration ("FDA") to expand the label indications for Acthar and cited Synacthen studies in its Acthar marketing materials.

7. Until June 2013, Novartis AG ("Novartis") marketed and sold Synacthen abroad.

8. In 2011, Novartis decided to sell the rights to market Synacthen in the United States. For years, Questcor had viewed Synacthen as a significant potential competitive threat to Acthar. In June 2013, Questcor outbid other companies to acquire the U.S. rights to Synacthen. Questcor's participation in the bidding process was a defensive move designed to protect its monopoly over ACTH drugs in the United States. By acquiring Synacthen, Questcor harmed competition by preventing another bidder from trying to develop the drug and launch it in the United States to challenge Questcor's monopoly over ACTH drugs.

II. The Parties

9. Plaintiff FTC is an administrative agency of the United States, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. §§ 41 et seq., with its principal offices at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580. The FTC is vested with the authority and responsibility for enforcing, inter alia, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to seek injunctive relief to prevent or remedy violations of any law the FTC enforces and to seek equitable remedies.

10. The Attorneys General of the Plaintiff States are the chief legal officers for their respective states. They are granted authority under federal antitrust law to bring actions for injunctive relief and under the laws of their respective states to bring actions to ensure compliance with their state laws and to enjoin violations of state law.

11. Defendant Mallinckrodt is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

12. Mallinckrodt acquired Questcor on August 14, 2014, for approximately $5.9 billion. At that time, Acthar was the only drug product sold by Questcor. With Mallinckrodt's acquisition, Questcor became a wholly owned subsidiary of Mallinckrodt and subsequently changed its corporate name from Questcor Pharmaceuticals, Inc. to Mallinckrodt ARD Inc.

13. Defendant Mallinckrodt ARD Inc. is a biopharmaceutical company incorporated in California and headquartered in Anaheim, California. The company manufactures and sells Acthar in the United States.

III. Jurisdiction and Venue

14. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

15. This Court has personal jurisdiction over Defendants pursuant to 15 U.S.C. § 53(b) because each Defendant has the requisite constitutional contacts with the United States of America.

16. In conjunction with the Commission, the Plaintiff States also bring this action for civil penalties and injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501, 45.50.551, 45.50.577 and 45.50.580, Md. Code Ann. Com. Law § 11-209, NY Gen. Bus. Law § 340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080. All claims under federal and state law are based upon a common nucleus of operative fact, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction over the non-federal claims under 28 U.S.C. § 1367(a), as well as

under principles of pendent jurisdiction.

17. Venue in this district is proper under Section 13(b)(2) of the FTC Act, 15 U.S.C. § 53(b), 15 U.S.C. § 22, and 28 U.S.C. § 1391(b), (c), and (d). Each Defendant resides, transacts business, or is found in this district.

18. Questcor and Mallinckrodt are, and at all relevant times have been, engaged in commerce or in activities affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12. Defendants also are, and at all relevant times have been, engaged in commerce in each of the Plaintiff States.

19. Questcor and Mallinckrodt are, and at all times relevant have been, a "corporation," as defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

IV. Questcor Possesses Monopoly Power With Acthar

20. Questcor has exercised, and continues to exercise, monopoly power in the United States with Acthar. The supracompetitive prices that Questcor charges for Acthar and its restriction of Acthar's output are direct evidence of this monopoly power. Questcor's monopoly power is also established by indirect evidence, which shows that Acthar holds a dominant share of the relevant market for ACTH drugs in the United States. That market is and has been characterized by substantial barriers to entry.

A. Direct Evidence of Acthar's Monopoly Power

21. Questcor has repeatedly and profitably raised Acthar's price substantially over the last decade. On August 27, 2007, Questcor increased the price of Acthar more than 1,300% overnight, from $1,650 to $23,269 per vial, causing its revenues to increase dramatically and its profits to soar. Additionally, Questcor has taken significant and profitable increases on eight occasions since 2011, pushing the price up another 46% to its current $34,034 per vial. Acthar

net sales grew from $218 million in 2011 to more than $1 billion in 2015.

22. Each alternative bidder expected to profitably sell Synacthen at a price well below Acthar's price, demonstrating that Acthar is currently priced at a supracompetitive level. The lower prices that would prevail in a duopoly market containing Acthar and Synacthen show that Acthar is currently extracting substantial monopoly rents.

23. Questcor restricts the output of Acthar by charging an extraordinarily high price, forcing third-party payers (e.g., health insurers) to limit Acthar's usage to the narrowest possible group of patients—those for whom no effective therapeutic alternatives exist. When Questcor implemented its 1,300% price increase in 2007, payers implemented formulary restrictions on Acthar. Most payers continue to impose stringent restrictions on Acthar. By setting a supracompetitive price and restricting the output of Acthar, Questcor has reduced market-wide output below competitive levels.

B. Indirect Evidence of Acthar's Monopoly Power

24. The relevant product market is ACTH drugs.

25. Questcor has encountered no competitive constraint on its ability to repeatedly and profitably increase Acthar's price and earn extremely high margins. Questcor does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications.

26. Acthar is indicated for the treatment of IS. Pediatric neurologists consider ACTH the gold standard treatment for IS. Other market participants—including doctors, third-party payers, and pharmaceutical companies (including Questcor)—agree. Treating an infant with IS using Acthar can cost more than $100,000. The only other treatment that is FDA-approved for

IS is Sabril, which has a completely different molecular structure and mechanism of action than Acthar and is used primarily in a discrete subset of IS patients. At approximately $25,000 per course of treatment, Sabril costs substantially less than Acthar. Although some doctors prescribe other treatments for a minority of IS patients, those treatments work differently than Acthar and are not substitutes for Acthar. Neither the price of Sabril nor the prices of other IS treatments have affected Acthar's pricing, and none of these other treatments constrains the price of Acthar.

27. Acthar is indicated for the treatment of IMN. Because of its high price, Acthar typically is prescribed only as a last-line therapy to treat IMN. A course of Acthar treatment for IMN can cost hundreds of thousands of dollars. Nephrologists prescribe low-cost, generic oncology agents or immunosuppressants as first and second-line therapies to treat most IMN patients. If those therapies fail or cannot be tolerated, some doctors may prescribe the drug Rituxan, whose costs can range from approximately $13,000 to $40,000 for a course of treatment. Because Acthar functions differently than any of these other therapies, doctors and payers do not consider these therapies substitutes for Acthar, and the price of Acthar is not constrained by any of these treatments.

28. Acthar is indicated for the treatment of other indications, including MS flare-ups and rheumatology conditions. For these indications, the price of Acthar is unconstrained by other drugs used to treat those conditions.

29. Even if Synacthen were approved by the FDA for only one of Acthar's indications, Synacthen would compete directly with Acthar and would be properly included in the relevant market. Synacthen is pharmacologically very similar to Acthar, as the active ingredient in both drugs is an ACTH molecule. Many doctors would prescribe Synacthen as a substitute for Acthar, and many payers would require its use in place of Acthar. Each alternative

purchaser of the Synacthen assets expected to compete head-to-head with Acthar and to take a substantial amount of Acthar's business with both on- and off-label sales.

30. The relevant geographic market is the United States. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S. consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

31. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

32. The U.S. ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's CEO has assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

V. Questcor Engaged in Anticompetitive Conduct By Acquiring Synacthen

33. Synacthen posed a threat to Questcor's ACTH drug monopoly, so Questcor intervened when other firms attempted to acquire the U.S. rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

A. Synacthen Posed a Nascent Competitive Threat to Acthar

34. Synacthen constituted a nascent competitive threat to Questcor's ACTH drug monopoly, notwithstanding the significant uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

35. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

36. In 2006, when Questcor decided to pursue an "orphan" (i.e., high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar's revenue growth.

37. In 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor. Unsuccessful in that attempt, Questcor continued to monitor the competitive threat from Synacthen.

38. In 2012, Questcor again concluded that Synacthen posed a threat to Acthar should it be approved for sale in the United States.

39. In 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could decimate its business.

40. But as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

B. Other Bidders Planned to Use Synacthen to Challenge Acthar's Monopoly

41. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug

was already approved and sold. Dozens of companies contacted Novartis and expressed interest in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

42. Each of the three firms planned to develop Synacthen for IS and/or IMN and use Synacthen to compete directly with Acthar. With approval for one or both of these indications, each firm expected to capture a significant share of the U.S. ACTH market from Questcor by pricing Synacthen well below Acthar. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the U.S. market.

C. The Value of the Synacthen Assets

43. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation has been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

44. The asset package sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

45. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation de novo, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

D. Questcor Disrupted the Synacthen Bidding Process

46. In October 2012, Questcor learned that at least one unidentified firm was attempting to acquire Synacthen from Novartis and develop it for the United States. Questcor immediately attempted to reach Novartis and shortly thereafter signed a confidentiality agreement with Novartis and submitted an offer for Synacthen.

47. Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company had exchanged deal terms with Novartis and had submitted a formal offer. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. Synacthen sales.

48. Unlike the three alternative bidders, Questcor had only inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis.

49. On June 11, 2013, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"), pursuant to which Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor is obligated to pay a minimum of $135 million, and likely will pay $300 million to Novartis for Synacthen.

E. Questcor's Acquisition of Synacthen Harmed Competition

50. Questcor's strategy to protect its monopoly position with Acthar was successful. But for Questcor's acquisition of Synacthen, one of the three alternative bidders would have acquired Synacthen and pursued its plan to develop Synacthen for IS and/or IMN to compete

directly with Acthar at a lower price. With the acquisition of Synacthen, Questcor thwarted a nascent challenge to its Acthar monopoly and thereby harmed competition.

51. Questcor claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the drugs' similarities, any therapeutic indication that Questcor pursues with Synacthen could have been pursued with Acthar.

52. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for $5.9 billion. The vast majority of Questcor's value was attributable to Acthar.

COUNT I – Monopolization in Violation of the FTC Act

53. Plaintiff the FTC re-alleges and incorporates by reference all of the allegations in the above paragraphs.

54. Defendants have, and at all relevant times had, monopoly power in the market for the sale of ACTH drugs in the United States.

55. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

56. Defendants' acts and practices are anticompetitive in nature and tendency and constitute unfair methods of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

COUNT II – Monopolization in Violation of the Sherman Act

57. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

58. Defendants have, and at all relevant times had, monopoly power in the market for

the sale of ACTH drugs in the United States.

59. Disrupting the bidding process for Synacthen and executing a license to the U.S. rights to Synacthen from Novartis eliminated the nascent competitive threat posed by an independently owned Synacthen and is conduct reasonably capable of contributing significantly to Questcor's maintenance of monopoly power.

60. Defendants' acts and practices constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT III – Supplemental State Law Claims

61. Plaintiff States re-allege and incorporate by reference all of the allegations in the above paragraphs.

62. The aforementioned practices by Defendants were and are in violation of Alaska's Restraint of Trade Act, Alaska Stat. §§ 45.50.562 et seq., Alaska's Unfair Trade Practices and Consumer Protection Act, Alaska Stat. §§ 45.50.471 et seq., and the common law of Alaska.

63. The aforementioned practices by Defendants were and are in violation of the Maryland Antitrust Act, Md. Code Ann., Com. Law §§ 11-201 et seq.

64. The aforementioned practices by Defendants were and are in violation of New York's antitrust law, the Donnelly Act, New York Gen. Bus. Law §340 et seq., and is proscribed by New York Executive Law 63(12), in that the aforementioned practices constitute illegality and/or illegal acts in the carrying on, conducting, or transacting of business.

65. The aforementioned practices by Defendants were and are in violation of Texas's Free Enterprise and Antitrust Act, Tex. Bus. & Com. Code Ann. §§ 15.01 et seq.

66. The aforementioned practices by Defendants were and are in violation of Washington's Consumer Protection Act, Wash. Rev. Code §§ 19.86 et seq., as proscribed by §

19.86.040, in that the aforementioned practices are unlawful in any part of trade or commerce.

Prayer for Relief

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), Section 16 of the Clayton Act, 15 U.S.C. § 26, Alaska Stat. §§ 45.50.501 and 45.50.580, Md. Code Ann. Com. Law § 11-209, New York Gen. Bus. Law §340 et seq., New York Executive Law 63(12), Tex. Bus. & Com. Code Ann. § 15.20, and Wash. Rev. Code § 19.86.080 empower this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, Plaintiffs request that this Court enter final judgment against Defendants Mallinckrodt and Questcor:

1. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a),

2. Adjudging that Defendants' conduct constitutes monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

3. Adjudging that Defendants have committed violations of each of the state laws enumerated in Count III;

4. Ordering that Defendants are permanently enjoined from engaging in similar and related conduct in the future;

5. Ordering divestiture and any further actions needed to restore competition lost due to the Defendants' violations;

6. Granting such other equitable relief as the Court finds necessary, including equitable monetary relief, to redress and prevent recurrence of Defendants' violations of Section 5(a) of the FTC Act, Section 2 of the Sherman Act, and the state laws enumerated in Count III,

as alleged herein;

7. Ordering Defendants to pay civil penalties pursuant to Alaska Stat. §§ 45.50.551(b) and 45.50.578(b)(2), Md. Code Ann., Com. Law § 11-209(a)(4), New York Gen. Bus. Law §342-a, Tex. Bus. & Com. Code Ann. §15.20(a), and Rev. Code of Wash. Ann. § 19.86.140; and

8. Awarding the Plaintiff States the costs of this action, including reasonable attorneys' fees and costs, as provided for in the Clayton Act and applicable state law.

Dated: January 18, 2017

Respectfully Submitted,

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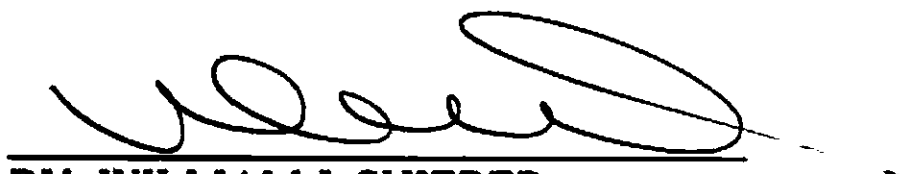

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FILED

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

RETROPHIN, INC., a Delaware Corporation,

Plaintiff,

vs.

QUESTCOR PHARMACEUTICALS, INC., a California Corporation,

Defendant.

SACV14-00026-JLS (JPRx)

COMPLAINT FOR:

1. **RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT (15 U.S.C. § 1 ET SEQ.)**
2. **MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2 ET SEQ.)**
3. **ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT (15 U.S.C. § 2 ET SEQ.)**
4. **UNLAWFUL MERGER IN VIOLATION OF SECTION 7 OF THE CLAYTON ACT (15 U.S.C. § 18 ET SEQ.)**
5. **VIOLATION OF CALIFORNIA ANTITRUST LAWS**
6. **VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAWS**

DEMAND FOR JURY TRIAL

JAN - 7 2014
Clerk, U.S. District Court
SOUTHERN DIVISION

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Plaintiff Retrophin, Inc. ("Retrophin"), as and for its complaint against Defendant Questcor Pharmaceuticals, Inc. ("Questcor"), alleges as follows:

Nature of the Action

1. Questcor is a monopolist. It is the sole provider in the US of approved therapeutic preparations of adrenocorticotropic hormone ("ACTH"), a drug used to treat certain life threatening and often fatal diseases. Questcor's ACTH drug is sold under the brand name H.P. Acthar Gel ("Acthar"). The drug is not patented.

2. Questcor acquired the rights to Acthar in 2001. At the time, Acthar sold for $50 a vial or less. Since then, Questcor has raised the price to $28,000 – a 56,000% price increase.

3. Questcor is able to charge such an extortionate price for Acthar because it holds a monopoly in the US. Its monopoly exists for several reasons. First, Acthar is the only long acting ACTH therapeutic drug approved by the Food and Drug Administration ("FDA") for use in the US. Second, Acthar is the most effective and dominant first line treatment for Infantile Spasms, an often fatal disorder that causes epileptic type seizures in babies, toddlers and children under the age of 5. In addition, Questcor has obtained "Orphan Drug Designation" for Acthar from the FDA under the Orphan Drug Act, 21 USC §§301 *et seq.*, giving it the exclusive right to market Acthar – and its chemical equivalent – for use in treating Infantile Spasms. Third, Acthar is also the most commonly used treatment of last resort for patients suffering from Nephrotic Syndrome, a condition that results in excessive protein being secreted through the urine that destroys the kidneys and can lead to kidney failure. Treatments of last resort, as the term implies, are used for patients who do not respond to or cannot tolerate other therapies used to treat their illness.

4. In June of 2013, plaintiff Retrophin was poised to challenge Questcor's monopoly. It had negotiated an agreement to purchase from Novartis AG ("Novartis"), the rights to sell in the US a product called Synacthen, an ACTH drug that contains the same sequence of the first 24 amino acids that is found in Acthar.

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While there are differences between Acthar and Synacthen – the two are not chemically identical beyond the first 24 amino acids and they are produced differently – Synacthen has been sold for years outside of the US for the treatment of Infantile Spasms, Nephrotic Syndrome, Multiple Sclerosis and other diseases. On information and belief, it is not currently sold in the US because it has never been submitted to the FDA for approval.

5. Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questor by dramatically undercutting Questcor's price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.

6. On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In so doing, it preserved and entrenched its ACTH monopoly in the US and eliminated the competitive threat posed by Retrophin's acquisition of Synacthen. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

7. When it acquired the rights to Acthar, Questcor did not make a Premerger Notification Filing with the Department of Justice and the Federal Trade Commission under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 USC, §18a *et seq.*

8. Questcor was quite aware, however, that its agreement with Novartis raised serious antitrust questions. The agreement provides that, if Questcor is forced to divest its rights to Synacthen on antitrust grounds, Novartis will keep the entire $60 million that Questcor had paid it. In addition, Questcor remains obligated to make all future milestone payments owed to Novartis under that agreement – an amount in excess of $75 million. Questcor has accepted the entire economic risk – an amount in

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excess of $135 million – that the agreement with Novartis would be deemed illegal under the antitrust laws.

9. Questcor's acquisition of Synacthen has delayed, and may completely foreclose, Retrophin's entry into the markets defined below. It will delay, and may completely prevent, Retrophin from competing against Questcor. Retrophin brings this lawsuit to recover the damages it has incurred as a result of Questcor's anticompetitive and monopolistic conduct. It also seeks injunctive relief against Questcor's continuation of such conduct.

The Parties

10. Plaintiff Retrophin is organized and exists under the laws of Delaware. Its principal place of business is located at 777 Third Avenue, 22nd Floor, New York, New York 10017. It also does business in California and Massachusetts.

11. Retrophin is a biopharmaceutical company focused on the development, acquisition and commercialization of drugs for the treatment of serious, catastrophic or rare diseases for which there are currently no viable options for patients. The diseases on which Retrophin focuses are often considered "orphan" diseases because they affect fewer than 200,000 patients in the United States. Retrophin has acquired and is building a pipeline of innovative product candidates for several catastrophic diseases, including: Focal Segmental Glomerulosclerosis, a kidney disease; Pantothenate Kinase-Associated Neurodgeneration; and Duchenne Muscular Dystrophy.

12. Defendant Questcor is a corporation organized and existing under the laws of the State of California. It maintains its principal place of business in Anaheim, California.

Jurisdiction and Venue

13. Retrophin brings this action under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§15 and 26, to recover treble damages and costs of suit, including reasonable attorneys' fees, and for injunctive relief, for injuries suffered by Retrophin

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alleged herein and arising from Questcor's continuing violations of Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 7 of the Clayton Act, 15 U.S.C. § 18. Jurisdiction for this action is invoked under Sections 4 and 16 of the Clayton Act, as amended, 15 U.S.C. §§ 15 and 26, and 28 U.S.C. §§ 1331 and 1337(a).

14. Additionally, this Court has diversity jurisdiction over this action pursuant to 28 U.S.C. § 1332(a) because the controversy exceeds the sum or value of $75,000 and Retrophin and Questcor are citizens of different states. This Court has supplemental jurisdiction over Retrophin's state law claims pursuant to 28 U.S.C. § 1367(a).

15. Venue in this Court exists by virtue of Sections 4 and 12 of the Clayton Act, as amended, 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391(c). Defendant Questcor is found, has agents, transacts and is doing business in this District, and the unlawful activities complained of herein were carried on, in substantial part, within this District.

16. Defendant is subject to personal jurisdiction in this Court because it resides in this District and transacts business in this District.

Trade and Commerce

17. The pharmaceutical products at issue in this case are sold in Interstate Commerce, and the unlawful activities alleged in this Complaint have occurred in, and have had and will have, a substantial effect upon, Interstate Commerce.

The Relevant Markets

18. There are a number of separate relevant product markets at issue in this case. They include: (a) the market for ACTH therapeutic drugs (the "ACTH Therapeutic Drug Market"); (b) the market for first-line drug treatments for Infantile Spasms (the "Infantile Spasms Market"); and (c) the market for treatments of last resort for Nephrotic Syndrome for those patients who do not respond to or cannot tolerate primary and secondary treatments for that disease (the "Nephrotic Syndrome

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Market"). The relevant geographic markets for each of these three relevant product markets is the United States, since drugs available in any of these markets are subject to FDA regulation. The ACTH Therapeutic Drug, Infantile Spasms, and Nephrotic Syndrome Markets are collectively referred to as the "Relevant Markets."

The ACTH Therapeutic Drug Market

19. ACTH is a drug used to treat certain life threatening and often fatal diseases, including Infantile Spasms and Nephrotic Syndrome. It is a polypeptide tropic hormone produced and secreted by the anterior pituitary gland. In the human body, ACTH activates the Melanocortin System and is referred to as a "Melanocortin agonist." The Melanocortin System affects a wide array of bodily functions ranging from skin pigmentation, inflammation, energy homeostasis and sexual function. As a consequence, ACTH can be used as a therapy for a variety of illnesses resulting from improper functioning of the Melanocortin System, including Infantile Spasms and Nephrotic Syndrome. There is no reasonable interchangeability between drug therapies used to treat other diseases and ACTH drug therapies used to stimulate the Melanocortin System.

20. Acthar is an ACTH. It is the only FDA approved long-acting ACTH available in the US. It is also the only FDA approved long-acting melanocortin agonist available in the US.

21. ACTH products have been approved for use as diagnostic agents which are used to test for the presence of certain conditions or diseases. However, those products are short acting and are not used as therapies in treating illnesses.

22. Consumers faced with a small but significant non-transitory increase in the price of ACTH therapeutic drugs, cannot and will not shift to other classes of drugs such that the increase in price will be rendered unprofitable. This is evidenced by the fact that Questcor, the only supplier of ACTH for therapeutic purposes in the US, has raised the price of a vial of Acthar to $28,000 and is able to maintain that price.

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23. FDA regulation and the difficulty of developing and manufacturing ACTH based therapeutic drugs reduce or eliminate any "supply elasticity" whereby manufacturers of other drug therapies convert their existing manufacturing facilities to the manufacture of ACTH therapeutic drugs.

24. The relevant geographic market for ACTH therapeutic drugs is national because therapeutic ACTH drugs cannot be sold in the US without FDA approval.

The Infantile Spasms Market

25. Babies and little children suffering from Infantile Spasms must have treatments that cure that affliction. Without it they suffer from epileptic type seizures and other symptoms of the disease. If untreated, they may suffer permanent brain or neurological damage and may develop other seizure disorders. The disease can be fatal. Only therapies that treat Infantile Spasm Syndrome can meet the medical needs of these patients. Therapies for other diseases do not cure or control Infantile Spasms and are not substitutes for Infantile Spasm therapeutics. There is no reasonable interchangeability between drug therapies used to treat other diseases and drug therapies used to treat children with Infantile Spasms.

26. Consumers faced with a small but significant non-transitory increase in the price of therapeutic drugs to treat Infantile Spasms, cannot and will not shift to other drug treatments for Infantile Spasms such that the increase in price will be rendered unprofitable. This is evidenced by the fact that Questcor has raised the price of a vial of Acthar to $28,000 and is able to maintain that price.

27. There are also regulatory entry barriers that limit the Relevant Market to first line therapies for Infantile Spasms. In 2010, Questcor obtained from the FDA, "Orphan Drug designation" for Acthar for Infantile Spasms under the Orphan Drug Act. Despite the fact that Acthar is not patented, the Orphan Drug designation gives Questcor a seven year exclusive right to sell Acthar, and its chemical equivalent, for Infantile Spasms with immunity from generic competition. Questcor's exclusive marketing right extends to 2017. Therapies that are excluded by Acthar's Orphans

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Drug Designation (generic versions of Acthar) cannot be labeled or marketed for the treatment of Infantile Spasms.

28. FDA regulation and the difficulty of developing and manufacturing treatments for Infantile Spasms preclude any "supply elasticity" whereby manufacturers of other drug therapies convert their manufacturing facilities to the manufacture of Infantile Spasm therapies.

29. The relevant geographic market for first line Infantile Spasm drug therapies is national because therapeutic drugs cannot be marketed in the US for Infantile Spasms without FDA approval.

The Nephrotic Syndrome Market

30. Nephrotic Syndrome is a condition in which excessive amounts of protein pass through the kidneys and are secreted through the urine. This results in kidney damage and can lead to kidney failure. Nephrotic Syndrome is treated on a first and second line basis with corticosteroids, such as Prednisone, or immunosuppressant drugs. In some patients the disease does not respond to these treatments and in others the patient cannot tolerate the drugs' side effects. In such cases, ACTH (Acthar) is the primary and dominant treatment of last resort. Only therapies that treat Nephrotic Syndrome effectively can meet the medical needs of Nephrotic Syndrome patients who do not respond to or cannot tolerate traditional first and second line therapies for that illness. Therapies for other diseases do not cure or control Nephrotic Syndrome and are not substitutes for last resort treatments for Nephrotic Syndrome. There is no reasonable interchangeability between drug therapies used to treat other diseases and drug therapies used to treat victims of Nephrotic Syndrome.

31. Consumers faced with a small but significant non-transitory increase in the price of last resort therapeutic drugs to treat Nephrotic Syndrome cannot and will not shift to other drug treatments such that the increase in price will be rendered

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unprofitable. This is evidenced by the fact that Questcor has raised the price of a vial of Acthar to $28,000 and is able to maintain that price.

32. There are also regulatory entry barriers that limit the Relevant Market to therapies of last resort for Nephrotic Syndrome. Therapies for other conditions cannot be marketed for the treatment of Nephrotic Syndrome without FDA approval. In addition, it is particularly difficult for the maker of a generic drug to obtain FDA approval when it is trying to prove that its synthetically manufactured product, which is manufactured in a laboratory setting, is the biopharmaceutical equivalent of a drug such as Acthar which is produced from animals.

33. FDA regulation and the difficulty of developing and manufacturing treatments for Nephrotic Syndrome preclude any "supply elasticity" whereby manufacturers of other drug therapies convert their manufacturing facilities to the manufacture of Nephrotic Syndrome therapies.

34. The relevant geographic market for therapies of last resort for Nephrotic Syndrome is national because such therapies cannot be marketed in the US for Nephrotic Syndrome without FDA approval.

Questcor Has Market and Monopoly Power in the Relevant Markets

35. There are no meaningful substitutes for Acthar or ACTH in the Relevant Markets. Nor are manufacturers of other pharmaceutical products able to shift their production to the manufacture of Acthar or other ACTH products. Even if they were able to do so, they could not sell those products without first obtaining FDA approval. Questcor has market and monopoly power in all of the Relevant Markets.

36. Questcor's monopoly power in all three of the Relevant Markets is further evidenced by a single price increase that it imposed in 2007. In that year, Questcor raised the price of Acthar from $1,650 per vial to $23,000 per vial, an overnight increase of over 1,300%. Questcor's ability to make that price increase "stick" is conclusive evidence of its market and monopoly power.

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The ACTH Therapeutic Drug Market

37. In the ACTH Therapeutic Drug Market, Acthar is the only FDA approved long acting ACTH therapeutic drug available to consumers in the United States.

38. Questcor's market and monopoly power in the ACTH Therapeutic Drug Market is further protected by the fact that other chemical variations of ACTH for use as therapeutic drugs require FDA approval for sale in the United States.

39. Questcor effectively has 100% of the market for ACTH Therapeutic Drugs. It has market and monopoly power in that market which is dramatically demonstrated by its continued ability to charge $28,000 for a vial of Acthar.

The Infantile Spasms Market

40. In the Infantile Spasms Market, Acthar is considered the "gold standard" of treatment.

41. Questcor's market and monopoly power in the Infantile Spasms Market is protected by the Orphan Drug Designation that protects Questcor from generic competition to Acthar. Its monopoly position is further protected by the fact that alternative therapies, that would not be precluded by the Orphan Designation, require FDA approval if they are to be marketed as therapies for Infantile Spasms.

42. Questcor admits that it has more than 50% share of the Infantile Spasms Market and its actual market share may be far greater. Questcor's market and monopoly power in the Infantile Spasms Market is demonstrated dramatically by its continued ability to charge $28,000 for a vial of Acthar.

The Nephrotic Syndrome Market

43. In the Nephrotic Syndrome Market, Acthar is the primary and dominant treatment of last resort for Nephrotic Syndrome patients who do not respond to or cannot tolerate first or second line treatments for that disease.

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44. Questcor's market and monopoly power in the Nephrotic Syndrome Market is further protected by the fact that alternative drug therapies require FDA approval if they are to be marketed as therapies for Nephrotic Syndrome.

45. Questcor's market and monopoly power in the Nephrotic Syndrome Market is demonstrated dramatically by its continued ability to charge $28,000 for a vial of Acthar.

Retrophin's Acquisition of Synacthen Threatened Questcor's Monopoly

46. Synacthen is an ACTH derivative that has been sold for years outside of the US and has been used successfully to treat patients with Infantile Spasms and Nephrotic Syndrome in other countries. It has not been commercially developed in the US and it has not been submitted to the FDA for approval for therapeutic use.

47. Synacthen is similar, but not chemically identical, to Acthar. Both drugs share the identical sequence of the first 24 amino acids in their respective molecules. This sequence of amino acids gives both drugs their therapeutic properties. Acthar, however, has a longer amino acid chain. The two drugs are also produced in very different ways. Acthar is "porcine derived." It is extracted from the pituitary gland found in the brains of slaughtered pigs. Synacthen, by contrast, is synthetically manufactured in a laboratory setting. These differences give Synacthen three competitive advantages over Acthar. First, Synacthen is less expensive to manufacture. Second, because it is manufactured in a controlled setting, the product is less susceptible to variation. Third, consumers are more comfortable knowing that the drugs they are taking – or giving to their infants – are produced in a sterile environment rather than being derived from slaughtered animals.

48. Retrophin planned to purchase the rights to Synacthen, obtain FDA approval for its use as a therapeutic, and enter the Relevant Markets in competition with Questcor. Retrophin planned to price Synacthen at a fraction of the price charged by Questcor and use its competitive pricing and Synacthen's other competitive advantages to take substantial market share from Acthar.

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49. In the late summer of 2012, Retrophin entered negotiations with Novartis to purchase the rights to manufacture and sell Synacthen in the US. After approximately nine months of due diligence and negotiations, Retrophin and Novartis agreed to terms on which Retrophin would acquire the rights to Synacthen. Final documents had been prepared and were merely awaiting the parties' signatures. The signing was set for June 11, 2013. Retrophin had prepared a press release announcing the deal.

50. In anticipation of the transaction, Retrophin had prepared a plan to obtain regulatory approvals for, and sell Synacthen. It devised a strategy for going directly to Phase III clinical drug trials in order to obtain FDA approval for the use of Synacthen to treat Infantile Spasms and Nephrotic Syndrome. It also planned to file a Treatment Investigational New Drug Application which, if approved by the FDA, would have allowed Retrophin to offer Synacthen to patients for free while it was awaiting FDA approval to market Synacthen for Infantile Spasms and Nephrotic Syndrome. This would have given patients immediate relief from Questcor's pricing and would have developed substantial goodwill for Retrophin and Synacthen in both the patient and medical communities. Retrophin believed that the history of Synacthen's use in other countries would aid it in obtaining FDA approval.

51. In anticipation of the product launch, Retrophin had put in place a clinical apparatus to conduct clinical trials necessary to obtain FDA approval. It planned to begin to market Synacthen upon FDA approval.

52. Given its expertise as a biopharmaceutical company focusing on rare diseases, Retrophin was ready, willing and able to enter the Relevant Markets with Synacthen subject to FDA approval. Retrophin's entry into the Relevant Markets would have broken Questcor's monopoly. The result would have been unambiguously procompetitive. Retrophin's entry into the market and its introduction of Synacthen as an alternative to Acthar would have benefitted all participants in the markets – other than Questcor. Prices to patients and payors would have dropped;

patients who were unable to pay for the drug would have been able to get it; other patients who were forced by Questcor's pricing to limit their dosages of the drug would have been able to take the medically prescribed amounts; and Retrophin would have earned substantial profits from sales of its product.

Questcor Illegally Acquires Synacthen to Preserve its Monopoly

53. Faced with a direct threat to its monopoly, Questcor acted to preserve its market dominance and its ability to charge extraordinary prices for Acthar. It swept in and secretly negotiated a deal to buy the rights to Synacthen from Novartis.

54. On June 11, 2013, the very day that Retrophin and Novartis were to sign their agreement, Questcor acquired the rights to Synacthen. The acquisition was closed on the day of the announcement. Questcor made no Premerger Notification filing with the Department of Justice and the Federal Trade Commission under the Hart Scott Rodino Act Antitrust Improvements Act of 1976. Nor did it observe the waiting period provided by the Hart Scott Act before closing the acquisition.

55. As part of the Agreement, the entire risk of an antitrust challenge to the transaction is borne by Questcor. The Agreement between Novartis and Questcor provides that Novartis receives the full consideration it is entitled to from Questcor even if the US antitrust enforcement agencies (The Federal Trade Commission or the Department of Justice) force Questcor to divest its rights in Synacthen. If such a divestiture occurs, the Agreement provides that Novartis keeps the entire $60 million that Questcor has paid it and Questcor will make all future milestone payments required by the Agreement – an amount in excess of $75 million. In short, the acquisition of the rights to Synacthen was so important to Questcor that it put at least $135 million at risk to keep Synacthen out of Retrophin's hands. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

56. Questcor's acquisition of the rights to Synacthen unreasonably restrained trade, maintained Questcor's monopolies and may result in a substantial lessening of competition in the Relevant Markets. As a result of Questcor's acquisition of the

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rights to Synacthen, prices to patients and payors for Acthar will remain at monopoly levels; patients who are unable to pay for the drug will not be been able to get it; other patients who are forced by Questcor's pricing to limit their dosages of the drug will not be able to take the medically prescribed amounts; and Retrophin will not earn the substantial profits it expected to earn from selling Synacthen at a fraction of the price Questcor charges for Acthar.

Retrophin Is Continuing to Try to Enter the Relevant Markets

57. Despite Questcor's anticompetitive and monopolistic conduct, Retrophin is continuing to try to enter the Relevant Product Markets. To that end, it has taken the highly unusual step of trying to create from scratch a drug – that it has designated as RE-034 – that will match Synacthen. Retrophin is endeavoring to create a new formulation of the drug that will incorporate the same active pharmaceutical ingredient used in Synacthen and match Synacthen's therapeutic effects for patients suffering from Infantile Spasms and Nephrotic Syndrome.

58. Retrophin's efforts to develop RE-034 will take substantial time and money and will require FDA approval. It will also require that the drug successfully complete both Phase I and Phase III clinical trials for both Infantile Spasms and Nephrotic Syndrome. There is no guarantee that RE-034 will succeed in the clinical trials or that Retrophin will succeed in obtaining FDA approval or entering the Relevant Markets.

59. Entering the Relevant Markets through RE-034 is more difficult, risky and time consuming than entering those markets through Synacthen. Synacthen is an existing product that has been manufactured and used outside of the US for decades in the treatment of a variety of illnesses, including Infantile Spasms and Nephrotic Syndrome. The owner of the rights to Synacthen has the information, know-how and ability to manufacture the drug and has decades of clinical data from outside the United States that can be used to facilitate and speed the regulatory approval process

in the US. Retrophin will need to develop all of that knowledge from scratch in seeking to enter the Relevant Markets with RE-034.

60. Entering the Relevant Markets through RE-034 will be more difficult, less likely to succeed and take longer than entry into those markets through the acquisition of Synacthen. Questcor's conduct has delayed, and may entirely foreclose, Retrophin from entering the Relevant Markets.

Questcor Has Damaged Competition in the Relevant Markets and Has Caused Retrophin to Suffer Both Injury in Fact and Antitrust Injury

61. Questcor's unlawful acquisition of the rights to Synacthen has foreclosed or delayed Retrophin from entering the Relevant Markets, has restrained trade, and has preserved and entrenched Questcor's monopoly and may substantially lessen competition. As a result, competition in the Relevant Markets has been damaged and Retrophin has been injured. Those injuries are intertwined and inseparable. Excluding or delaying Retrophin from entering the Relevant Markets with Synacthen was and is an integral aspect of Questcor's anticompetitive conduct.

62. Retrophin has suffered and continues to suffer injury in fact from Questcor's acquisition of the rights to Synacthen and the preservation of its monopoly.

63. Retrophin has suffered and continues to suffer antitrust injury from Questcor's acquisition of the rights to Synacthen and the preservation of its monopoly. Retrophin has been injured directly as a result of Questcor's unlawful conduct. Retrophin is a potential entrant into the Relevant Markets and, but for Questcor's unlawful conduct, would be entering those markets with Synacthen. There are no aspects of Questcor's conduct that are beneficial to competition. Retrophin's injury is an integral aspect of Questcor's unlawful conduct; flows from that which renders Questcor's conduct unlawful; and its injury is of the type the antitrust laws were intended to prevent.

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FIRST CAUSE OF ACTION

(COMBINATION IN THE RESTRAINT OF TRADE IN VIOLATION OF SECTION 1 OF THE SHERMAN ACT)

64. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 63 as if fully set forth herein.

65. In acquiring the rights to Synacthen, Questcor entered into a contract, conspiracy or combination that unreasonably restrains trade in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

66. Questcor's acquisition of the rights to Synacthen unlawfully and unreasonably restrains trade by preventing or delaying Retrophin from entering the Relevant Markets and challenging Questcor's market power in those markets.

67. Questcor's violation of Section 1 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

68. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

SECOND CAUSE OF ACTION

(MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT)

69. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

70. Questcor has monopoly power in the Relevant Markets. In acquiring the rights to Synacthen in the US, Questcor has intentionally acted to maintain and entrench its monopoly position in Relevant Markets, and has done so, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

71. Questcor's violation of Section 2 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

72. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

THIRD CAUSE OF ACTION

(ATTEMPTED MONOPOLIZATION IN VIOLATION OF SECTION 2 OF THE SHERMAN ACT)

73. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 72 as if fully set forth herein.

74. In acquiring the rights to Synacthen, Questcor has engaged in monopolistic and anticompetitive conduct with the specific purpose and intent of monopolizing the Relevant Markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

75. The sole purpose of Questcor's acquisition of the rights to Synacthen is to enable Questcor to gain or maintain a monopoly position in the Relevant Markets.

76. A dangerous probability exists that Questcor has succeeded, and if not restrained, will continue to succeed in monopolizing the Relevant Markets.

77. Questcor's acts of attempted monopolization has unlawfully prevented and delayed Retrophin from entering the Relevant Markets and otherwise injure competition in those markets by reducing choice, inflating prices, and lessening innovation.

78. Questcor's violation of Section 2 of the Sherman Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

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79. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

FOURTH CAUSE OF ACTION

(UNLAWFUL MERGER IN VIOLATION OF SECTION 7 OF THE CLAYTON ACT)

80. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 79 as if fully set forth herein.

81. Questcor's acquisition of the rights to Synacthen is likely to substantially lessen competition in interstate trade and commerce in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

82. Questcor's acquisition of the rights to Synacthen is likely to result in a substantial lessening of competition in the Relevant Markets.

83. Questcor's violation of Section 7 of the Clayton Act has caused, and will cause, damages to Retrophin in an amount to be determined at trial, such damages to be trebled in accordance with Section 4 of the Clayton Act, 15 U.S.C. § 15.

84. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

FIFTH CAUSE OF ACTION

(VIOLATION OF CALIFORNIA ANTITRUST LAWS)

85. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 84 as if fully set forth herein.

86. In acquiring the rights to Synacthen, Questcor entered into and engaged in a continuing unlawful trust in restraint of the trade and commerce described above in violation of the California antitrust laws referenced below. Questcor has acted in violation of these laws in an effort to maintain, entrench, and/or create a monopoly,

and otherwise injure competition in the Relevant Markets. Questcor's conduct substantially affected commerce in California.

87. In acquiring the rights to Synacthen in the US, Questcor has maintained and entrenched its monopoly position in the Relevant Markets.

88. Questcor's acquisition of the rights to Synacthen is likely to result in a substantial lessening of competition in the Relevant Markets.

89. By reason of the foregoing, Questcor violated California's Cartwright Act, California Business and Professions Code §§ 16720 *et seq.*

90. Questcor's violation of California's Cartwright Act, California Business and Professions Code §§ 16720 *et seq.* has caused, and will cause, damages to Retrophin in an amount to be determined at trial, with such damages to be trebled.

91. Questcor's unlawful conduct is ongoing, irreparably injures Retrophin, harms the public interest, and unless restrained will continue. Retrophin has no adequate remedy at law.

SIXTH CAUSE OF ACTION

(UNFAIR COMPETITION UNDER CAL. BUS. & PROF. CODE § 17200 *ET SEQ.*)

92. Retrophin repeats and realleges the allegations set forth in paragraphs 1 through 91 as if fully set forth herein.

93. California Unfair Competition Law, Business and Professions Code Section 17200 *et seq.*, provides that "unfair competition shall mean and include any unlawful, unfair or fraudulent business act."

94. Questcor's conduct as alleged herein meets the "unlawfulness" prong of California Business and Professions Code §§ 17200 *et seq.* Questcor has committed and continues to commit unlawful business practices by illegally acquiring the rights to Synacthen and engaging in anticompetitive and monopolistic conduct in violation of antitrust laws.

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95. Questcor's conduct as alleged herein also meets the "unfair" prong of California Business and Professions Code §§ 17200 *et seq*. Questcor's anticompetitive and monopolistic conduct harms the public interest, threatens an incipient violation of an antitrust law and/or violates the policy or spirit of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition.

96. Pursuant to California Business and Professions Code § 17203, Retrophin seeks the disgorgement of Questcor's profits earned by its unlawful and/or unfair business practices to the extent it constitutes restitution to Retrophin.

97. Pursuant to California Business and Professions Code § 17203, Retrophin seeks an order of this court enjoining Questcor from continuing to engage, use, or employ the unlawful and/or unfair business practices complained of herein.

98. Questcor's wrongful conduct has caused and, if it continues, will continue to cause irreparable harm to Retrophin that cannot be fully compensated by money and for which Retrophin has no adequate remedy at law. Retrophin is thus entitled to permanent injunctive relief preventing Questcor from continuing to engage in the conduct alleged in this Complaint.

PRAYER FOR RELIEF

WHEREFORE, Retrophin respectfully demands judgment against Questcor:

A. DECLARING that Questcor's acquisition of the rights to Synacthen is an unlawful contract, combination or conspiracy in restraint of trade in violation of Section 1 of the Sherman Act;

B. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes unlawful monopolization of the Relevant Markets in violation of Section 2 of the Sherman Act;

C. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes an unlawful attempt to monopolize the Relevant Markets in violation of Section 2 of the Sherman Act;

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D. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes an acquisition that may result in a substantial lessening of competition in the Relevant Markets in violation of Section 7 of the Clayton Act;

E. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes an unlawful trust in restraint of trade and commerce in violation of California Business and Professions Code §§ 16720 *et seq.*;

F. DECLARING that Questcor's acquisition of the rights to Synacthen constitutes unfair competition in violation of California Business and Professions Code § 17200 *et seq.*;

G. PERMANENTLY ENJOINING Questcor from enforcing or maintaining its Rights to Synacthen under its agreement with Novartis or any similar formal or informal agreement;

H. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of Section 1 of the Sherman Act;

I. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of Section 2 of the Sherman Act;

J. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of Section 7 of the Clayton Act;

K. PERMANENTLY ENJOINING Questcor from engaging in further anticompetitive conduct in violation of California Business and Professions Code §§ 16720, *et seq.*;

L. PERMANENTLY ENJOINING Questcor from engaging in further unlawful and/or unfair business practices in violation of California Business and Professions Code § 17200 *et seq.*;

M. DISGORGING any profits generated by Questcor as a result of its unlawful and/or unfair business practices to the extent it constitutes restitution to Retrophin;

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N. AWARDING Retrophin damages in an amount to be proved at trial, such damages to be trebled, including its costs and attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15 and/or California's Cartwright Act, California Business and Professions Code §§ 16720, *et seq.*;

O. AWARDING Retrophin its costs, expenses and attorneys' fees incurred in connection with the action;

P. AWARDING Retrophin interest to the maximum extent permitted by law; and

Q. GRANTING Retrophin such other and further relief as this Court deems just and proper.

Dated: January 7, 2014

KATTEN MUCHIN ROSENMAN LLP

By: K. Holland

Kristin L. Holland
Attorneys for Plaintiff Retrophin, Inc.

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DEMAND FOR JURY TRIAL

Retrophin hereby demands a trial by jury on all of its claims and causes of action.

Dated: January 7, 2014

KATTEN MUCHIN ROSENMAN LLP

By: _____

Kristin L. Holland
Attorneys for Plaintiff Retrophin, Inc.

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UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I. (a) PLAINTIFFS (Check box if you are representing yourself ☐)

Retrophin, Inc.

DEFENDANTS (Check box if you are representing yourself ☐)

Questcor Pharmaceuticals, Inc.

(b) County of Residence of First Listed Plaintiff New York, NY
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Orange, CA
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

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Attorneys (*Firm Name, Address and Telephone Number*) If you are representing yourself, provide the same information.

N/A

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☐ 1. U.S. Government Plaintiff
- ☒ 3. Federal Question (U.S. Government Not a Party)
- ☐ 2. U.S. Government Defendant
- ☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES-For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☒ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☒ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1. Original Proceeding ☐ 2. Removed from State Court ☐ 3. Remanded from Appellate Court ☐ 4. Reinstated or Reopened ☐ 5. Transferred from Another District (Specify) ☐ 6. Multi-District Litigation

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

CLASS ACTION under F.R.Cv.P. 23: ☐ Yes ☒ No ☒ **MONEY DEMANDED IN COMPLAINT:** $ Over $75k, TBD

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)
Plaintiff is suing defendant for entering an illegal agreement and engaging in conduct that violates federal and state antitrust and competition laws, 15 U.S.C. §§ 1, 2, 18, and California Business and Professions Code §§ 16720, et seq, California Business and Professions Code §§ 17200, et seq

VII. NATURE OF SUIT (Place an X in one box only).

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☒ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/Etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Org.
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Info. Act
- ☐ 896 Arbitration
- ☐ 899 Admin. Procedures Act/Review of Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Vet.)
- ☐ 153 Recovery of Overpayment of Vet. Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment

REAL PROPERTY CONT.
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpratice
- ☐ 365 Personal Injury-Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accomodations
- ☐ 445 American with Disabilities-Employment
- ☐ 446 American with Disabilities-Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus/Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405 (g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405 (g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: 5:21-CV-00026

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII. VENUE: Your answers to the questions below will determine the division of the Court to which this case will most likely be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

Question A: Was this case removed from state court? ☐ Yes ☒ No If "no," go to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	STATE CASE WAS PENDING IN THE COUNTY OF:	INITIAL DIVISION IN CACD IS:
	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	Southern
	☐ Riverside or San Bernardino	Eastern

Question B: Is the United States, or one of its agencies or employees, a party to this action? ☐ Yes ☒ No If "no," go to Question C. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	If the United States, or one of its agencies or employees, is a party, is it:		
	A PLAINTIFF? Then check the box below for the county in which the majority of DEFENDANTS reside.	A DEFENDANT? Then check the box below for the county in which the majority of PLAINTIFFS reside.	INITIAL DIVISION IN CACD IS:
	☐ Los Angeles	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	☐ Orange	Southern
	☐ Riverside or San Bernardino	☐ Riverside or San Bernardino	Eastern
	☐ Other	☐ Other	Western

Question C: Location of plaintiffs, defendants, and claims? (Make only one selection per row)	A. Los Angeles County	B. Ventura, Santa Barbara, or San Luis Obispo Counties	C. Orange County	D. Riverside or San Bernardino Counties	E. Outside the Central District of California	F. Other
Indicate the location in which a majority of plaintiffs reside:	☐	☐	☐	☐	☒	☐
Indicate the location in which a majority of defendants reside:	☐	☐	☒	☐	☐	☐
Indicate the location in which a majority of claims arose:	☐	☐	☒	☐	☐	☐

C.1. Is either of the following true? If so, check the one that applies:

☒ 2 or more answers in Column C

☐ only 1 answer in Column C and no answers in Column D

Your case will initially be assigned to the SOUTHERN DIVISION.
Enter "Southern" in response to Question D, below.

If none applies, answer question C2 to the right. →

C.2. Is either of the following true? If so, check the one that applies:

☐ 2 or more answers in Column D

☐ only 1 answer in Column D and no answers in Column C

Your case will initially be assigned to the EASTERN DIVISION.
Enter "Eastern" in response to Question D, below.

If none applies, go to the box below. ↓

Your case will initially be assigned to the WESTERN DIVISION.
Enter "Western" in response to Question D below.

Question D: Initial Division?	INITIAL DIVISION IN CACD
Enter the initial division determined by Question A, B, or C above: →	Southern Division

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

IX(a). IDENTICAL CASES: Has this action been previously filed **in this court** and dismissed, remanded or closed? ☒ NO ☐ YES

If yes, list case number(s): _____

IX(b). RELATED CASES: Have any cases been previously filed **in this court** that are related to the present case? ☒ NO ☐ YES

If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)

- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☐ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☐ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

X. SIGNATURE OF ATTORNEY (OR SELF-REPRESENTED LITIGANT): K. Hollowell DATE: 1/7/2014

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet).

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))